

# Isolagen Experts Answer Key Clinical Questions

Editor's Note: This roundtable addresses critical questions regarding the clinical use of Isolagen, which is a unique facial rejuvenation process that involves injection of the patient's own fibroblast cells after laboratory cultivation. The Isolagen process is currently pending FDA approval in the U.S.

### What is your typical patient treatment protocol?

**Nancy Silverberg, M.D.** – For the Isolagen studies, we take a small skin biopsy: a 7 x 3 mm biopsy from behind the patient's ear, applying a little local anesthetic. It takes less than five minutes. After performing the punch biopsy, we put in a tiny stitch. We then overnight the biopsy specimen to the Isolagen laboratory.

We don't see the patient again for six to eight weeks because the patient's cells need to reach a critical number. Millions of living fibroblast cells are generated from the original sample in a cell culture. Once we are notified by the lab that the patient's cells have

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reached the appropriate level, we have one to two days to schedule the patient. The cells are express mailed to us so that they arrive the morning of the appointment.

We inject the new, living fibroblast cells into the patient that afternoon. The session lasts about as long as a typical injectable session, usually no longer than ten minutes. However, the technique is not a lot of little pokes. Usually, you simply push the needle in and inject as you withdraw. On average, there are two injec-

tions for each nasolabial fold and two for the glabella fold. We often use a topical anesthetic, but some of the other sites just use ice. Patients have a series of three visits, either weekly or every other week.

### How many patients have you treated to date and what kind of results are you achieving?

**Suzanne Bruce, M.D.** – I would estimate that over the past year we have treated 50 patients at our practice. We also biopsied another 50 patients in August for the beginning of a phase III pivotal study. Most of the patients are women in their forties, fifties and sixties with wrinkles.

My clinical impression is that some of the patients are definitely improving, but, of course, some of them are receiving placebo. Treatment also appears to be most effective in superficial lines. The clinical trials, though, limit the number of cells we can inject at one time. Once Isolagen is FDA approved, we'll be able to use more. Perhaps by injecting greater volume, we will achieve better results in patients with big, deep folds.

**Michael Macaluso (Board Member and former CEO of Isolagen)** – We retrospectively reviewed 396 patient charts from 1994 to 1999. We contacted many doctors who noted that patients had maintained results five years after injections. We are confident that Isolagen is a safe and simple procedure. Clinical trial investigators tell me patient satisfaction is high and the clinical response is promising.

**Dr. Silverberg** – Some patients see results within a few weeks, but typically it is more in the range of three to six months. And patients may continue to improve over the next year. However, we don't know if maintenance therapy is recommended. Virtually all our study patients have said they love their results and they want more cells for other wrinkles. Although the technology is probably going to be quite pricey, you do achieve long-lasting outcomes, so in the long run it may be less expensive.



### What are some other advantages of Isolagen compared to other facial fillers?

**Dr. Bruce** – The idea of injecting your own cells and tissue, as opposed to a foreign body, is very appealing to people. There is less worry about allergic reactions or foreign body reactions. There is also the hope of more longevity with treatment.

**Mr. Macaluso** – I am impressed that the product is self-healing, and not a filler. This is what initially attracted me to the company. Your own body has the ability to heal itself.

However, we are learning that results are technique dependent. Physicians with better technique seem to achieve superior results quicker. It is a matter of under-

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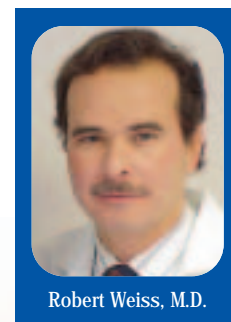
standing how and where the fibroblasts work best, and making sure we inject them in that part of the skin.

**Robert Weiss, M.D.** – It has actually been quite easy to recruit for the studies. I recently returned from a professional gathering in Vancouver, Canada, where doctors from England, Australia and New Zealand were in attendance. At dinner one night, the subject of Isolagen came up. The patients in these countries have an overwhelming desire to have their own cells injected, and even their own cells stored frozen. I understand that some international patients are scheduled out to April 2005.

### What about patients who desire immediate results?

**Dr. Bruce** – Patients can opt for a short-term filler while they're waiting for their cells to grow at the laboratory, if they have an important social event coming up, for example. Frankly, though, I rarely encounter a patient who needs an effect by next week. There are also lots of unanswered questions at this time, including how long the effect lasts and how many cells we should be injecting. The technology is still in its infancy, but it is very exciting and promising.

**Dr. Weiss** – The delay from biopsy to injection is not an obstacle or a hindrance to patients. The comfort level people have with their own cells and the potential for very long-term results make the technology highly desirable.



### What do you envision as future applications for Isolagen?

**Mr. Macaluso** – We believe that Isolagen may have medical applications down the road that are beyond the aesthetic dermatology arena, including urinary incontinence, oral cavity disease and non-healing wounds. I believe there is nothing more natural than using your own cells.

**Dr. Weiss** – If the data holds up for long-term and very gradual improvement, this technology would not be limited to treating isolated wrinkles. It might encompass total facial rejuvenation. Injections could possibly continue until all wrinkles or fine lines improve. Other areas of the body might also benefit from improved skin texture. Furthermore, combining Isolagen with light sources may speed up the results. ■

*\* At press time, Isolagen announced the appointment of Robert Bitterman as President and CEO. Mr. Macaluso remains involved with Isolagen as a member of the Board of Directors.*

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