Has Chronic Plantar Fasciitis Met Its Match?
Injectable human umbilical cord and amniotic membrane matrix delivers promising results.

BY JOLYNN TUMOLO

When David N. Garras, MD, an assistant professor at the University of Illinois at Chicago, proposed investigating the effects of an injectable human umbilical cord and amniotic matrix in patients with plantar fasciitis, he suspected the results would be good. But he didn’t expect them to be this good.

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“In a nutshell, it has surpassed our expectations of what it could do,” he said. “The results have been actually phenomenal. They’ve blown our minds.”

Dr. Garras, an orthopedic specialist at Midwest Orthopaedic Consultants in Chicago, had used Clarix® regenerative matrices in various foot and ankle surgeries and was a fan of the product. An enthusiastic researcher as well, he suggested to product developer Amniox Medical that some evidence documenting the injectable version’s efficacy might grab insurers’ attention and eventually convince them to cover its use. Amniox Medical agreed, and Dr. Garras joined Ryan T. Scott, DPM, of the CORE Institute in Phoenix, in a study testing the injectable Clarix Flo matrix for the treatment of plantar fasciitis.

“This is one of a couple of studies that we proposed, and the company thought it would be very exciting,” Dr. Garras said. “In order to make it a clean study, we all agreed that we would do this absolutely without any payment or funding from the company. We were not biased in any way.”

Although the data at press time was still undergoing final analysis, preliminary findings were announced at the American College of Foot and Ankle Surgeons conference in Las Vegas this spring: In 43 patients who had plantar fasciitis for at least 3 months, injections of Clarix Flo significantly decreased pain and boosted functional recovery. Considering the prevalence of plantar fasciitis (an estimated 2 million patients are treated for it annually, according to the

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American Academy of Orthopaedic Surgeons) and that a fraction of patients fail to get better with conservative treatments like physical therapy and anti-inflammatory medications, the future of the injectable human tissue matrix looks promising.

“It wasn’t long before Clarix Flo’s potential went from the merely theoretical to yielding results in actual patients with plantar fasciitis.

“Initially, we had some clinicians doing a few injections here and there, and we started to anecdotally see some good evidence,” said Dr. Raines. “That really expanded our thought into doing a research study.”

Enter Dr. Garras, Dr. Scott, and the study’s 43 patients seeking relief from plantar fasciitis pain and functional disability plaguing them for 3 months or more. In most cases, they had tried conservative treatments but failed to find relief, “bringing them,” Dr. Scott said, “to the injection crossroad.”

The Clarix Flo Difference

Corticosteroid injections can offer pain relief for plantar fasciitis when physical therapy and anti-inflammatories do not, but they come with potential complications, such as thinning or atrophy of the fat pad at the plantar heel and degenerative trauma or even rupture of the plantar fascia. The American Orthopaedic Foot & Ankle Society categorizes steroid injections not as a cure for plantar fasciitis, but as a pain reliever that lasts anywhere from 3-6 months.

Clarix Flo, on the other hand, aims to ease pain and disability through the injection of tissue particulates that promote regeneration and actual healing.

“Both the umbilical cord as well as the amniotic tissue have certain proteins that help modulate the type of inflammation formed. Inflammation can go down the pathway of either regenerative, meaning a healing inflam-
patient’s own platelet-plentiful blood is re-injected in an effort to promote healing.

“It’s really just kind of delivering a bolus of growth factors in an uncontrolled manner to stimulate an acute inflammatory response. But the problem with a lot of these patients is the reason they have plantar fasciitis is because their healing process is not working properly to begin with,” said Dr. Raines. “The advantage of using something like Clarix Flo is its ability to modulate the local environment. It’s not trying to create an uncontrolled inflammatory response but actually fundamentally altering the underlying biology to allow the body’s own healing responses to take over.”

According to Dr. Garras, although PRP injection is used commonly for plantar fasciitis, there’s a lack of science behind the procedure. What’s more, he added, it comes with a certain amount of morbidity from the blood draws as well as the possibility of infection from vial transfers and reinjection.

“PRP,” he said, “is not completely benign.”

**Patient Improvement with Clarix Flo**

In their study, Dr. Scott and Dr. Garras randomized patients to treatment with either 1 or 2 Clarix Flo injections spaced 6 weeks apart at doses of 25 mg, 50 mg, or 100 mg. While final results are pending, the early data are suggesting 2 injections of higher doses seemed to be most effective for pain relief and for improvement in Foot and Ankle Ability Measure (FAAM) index scores.

“It makes sense from a scientific perspective,” said Dr. Raines. “The first injection is getting in there and controlling that local degenerative, inflammatory environment, kind of slowing all that down. Then the second injection is really promoting the body’s regenerative healing response.”

That’s not to suggest lower doses used in the study were ineffective, Dr. Raines clarified.

“In all patients,” he said, “regardless of the amount of the injection—25 mg, 50 mg, or 100 mg—we saw significant improvement in their pain throughout the course of treatment as well as improvement in function as measured by the Foot and Ankle Ability Measure index.”

“I’m pretty sure almost 100% of my patients had some improvement. How significant of an improvement varied, of course,” said Dr. Garras. “On average, pain dropped from anywhere from 7 out of 10 on the pain scale to 1 out of 10 on the pain scale. That was an average, so there were a lot of people who had no pain whatsoever after treatment. There

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were people with functional scores that jumped dramatically. We were shocked at how it worked."

In most cases, it took 3-4 weeks for patients to get the results they wanted. That was the case with a

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Chicago SWAT team police officer who, Dr. Garras recalls, was side-lined for months by plantar fasciitis, put on desk duty, and “just going crazy.” The young officer was randomized to a 2-injection protocol of Clarix Flo and, within 4 weeks of the first injection, was off the desk and back in action with his SWAT teammates.

“He actually questioned whether or not he needed to get the second injection because he felt so great,” said Dr. Garras.

Another patient, a 50-year-old woman, turned to Clarix Flo after exhausting all other available treatment options over years of plantar fasciitis pain.

“Although not miraculous, she improved to the point where she had gotten back to activities that she had not done in over 3 years,” Dr. Garras said. “She was back to running, back to playing tennis. She told me she went on vacation, and she was able to walk on the beach for the first time without any pain.”

Cash-based Opportunity

The cost for an injection of Clarix Flo is well in line with the cost of a PRP injection, according to Dr. Raines. Like PRP, the cost of the injection is typically covered by the patient, but Amniox Medical plans to establish the product’s efficacy for plantar fasciitis with a second, larger clinical trial—and then target insurers with the necessary data to gain coverage.

Until then, patients will have to pay out of pocket for Clarix Flo. It’s something Dr. Garras said many are willing to do.

“I have had quite a few patients pay out of pocket for it,” he said, “simply because they’ve gotten to the point where nothing else has worked.”

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“Reviewing the cost of health care and the overall cost of the injection, it makes sense to offer the injection to patients suffering chronic plantar fasciitis,” said Dr. Scott. “Early intervention allows these patients to get back to activity faster.”

Other clinicians, and their patients, apparently share that view.

“We do have a lot of doctors who are seeing a pretty high volume of Clarix Flo injections,” added Dr. Raines. “And there are a lot more physicians out there who are adding this to their practice. I travel with our sales reps for various meetings and presentations in the field, and I see a good number of physicians starting to use the injectable. A lot of doctors have mentioned that they like it for plantar fasciitis because the patient’s pain seems to go down very quickly, and they’re seeing patients not coming back as frequently with recurring pain, which I think speaks of the strong regenerative potential of the tissue.”

According to Dr. Scott, Amniox Medical is working with physicians on a competitive, cost-based program to make Clarix Flo both affordable to patients and profitable for practices.

“From a practice management aspect, the injection program offered by Amniox could be very lucrative in ancillary income,” he said.

In other words, the product could be a win-win for podiatrists as well as their patients with plantar fasciitis that doesn’t respond to standard conservative treatment. Dr. Scott predicts Clarix Flo will become a primary treatment for patients with chronic plantar fasciitis. Dr. Garras thinks, eventually, it will either subsidize or replace the use of steroid injections altogether.

“Ultimately, I think Clarix Flo could really become one of the forefront therapies for plantar fasciitis for those patients who fail conservative traditional treatments rather than trying things like PRP, steroids, or surgery,” said Dr. Raines. “Clarix Flo could really be ‘The Treatment’ for a lot of patients.”

“Like I said,” added Dr. Garras, “none of us really expected dramatic improvements in such a short period of time. This was almost just a proof-of-concept trial to see if this really was going to work well. And it exceeded our expectations in so many ways. That’s why we’re talking about it now: It worked that well.” PM