

# Has Chronic Plantar Fasciitis Met Its Match?

Injectable human umbilical cord and amniotic membrane matrix delivers promising results.

BY JOLYNN TUMOLO

**W**hen 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.



David N. Garras, MD

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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 Amnio Medical that some evidence documenting the injectable version's efficacy might grab insurers' attention and eventually convince them to cover its use. Amnio 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,



Clarix Flo bottle with particulate

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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## New Concepts and Studies

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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.

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potential to completely revolutionize our current treatment algorithm for plantar fasciitis, tendinitis, and other painful conditions of the soft tissues and joints,” said Dr. Scott. “Clarix Flo is the cutting-edge use of biologics in the office setting.”

### **Particulate Clarix in an Injection**

Clarix Flo is a particulate form of the Clarix Cord 1K umbilical cord and Clarix 100 amniotic membrane regenerative matrix sheets, which are typically used in surgeries and wound care. All Clarix products are made from cryopreserved human amniotic membrane and umbilical cord, using Amnio Medical’s patented Cryotek processing method. Cryotek employs deep freezing to preserve tissue biology, function, and structural integrity while maintaining a natural hydrated state. According to the company, the method is proven to maintain the physical and biological properties of the tissue.

“Our chief scientific officer is an MD-PhD. His research has been funded by the National Institutes of Health for the past 30 years, and he has devoted a lot of those efforts toward the understanding of the biology of these tissues and their anti-inflammatory and anti-scarring action,” said Andrew Raines, PhD, senior research scientist at Amnio Medical, Atlanta. “These anti-inflammatory and anti-scarring actions are present in significantly greater quantities in the umbilical cord. So we’re harnessing the power of the umbilical cord to deliver even more of this biology. We’re currently the only company offering umbilical cord technology on the injectable market today.”

When Amnio Medical scientists floated the idea of an injectable Clarix several years ago, clinician feedback suggested a potential indication for plantar fasciitis.

“A lot of the doctors latched on to plantar fasciitis because there is a distinctive degenerative component to the disease along with an inflammatory component,” Dr. Raines explained. “Having the potential of these tissues to modulate that local environment, the plantar fascia, to really promote more regenerative healing—it was an interesting prospect from our doctors, and that’s where it got started.”

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**

Cortisone 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-



Andrew Raines, PhD

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mation toward an endpoint where things function as well as they did before the inflammation, or a destructive pathway, where it becomes a chronic inflammatory state that doesn’t actually repair. So you get this constant or chronic pain that needs something to revive it back into the acute inflammatory phase to help it heal,” said Dr. Garras. “Clarix has in it a group of proteins that helps direct toward a healing pathway. It’s not a miracle drug, and it’s not a pain medication, but it allows the body to heal itself.”

“The injection helps modulate inflammation and recruit new cells into the area for a regenerative effect,” Dr. Scott said. “As the plantar fascia continues to regenerate and ultimately heal, the pain is reduced and the patient is able to return back to full activity.”

Another injection-based intervention used to treat plantar fasciitis is platelet-rich plasma, or PRP, in which a

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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 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 cer-

tain 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

“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 ex-

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 Amnio 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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Chicago SWAT team police officer who, Dr. Garras recalls, was sidelined 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.

hausting 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

“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 periods 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**



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