VERMONT REGENERATIVE MEDICINE
JONATHAN E. FENTON, D.O., F.A.A.P.M.&R.

Board Certified in:
Physical Medicine and Rehabilitation
Neuromusculoskeletal Medicine
Orthopaedic Medicine
Musculoskeletal Ultrasound

Practice limited to:
Osteopathic Physical Medicine
Image Guided Injections
Interventional Regenerative Orthopedic Medicine

A Physician Examines Bogus Claims Made by Amniotic and Cord Stem Cell Providers

Many chiropractors and other providers who use amniotic and cord products for musculoskeletal issues claim these products have “live stem cells” because someone told them they did. In reality, just claiming these products have live cells would require an FDA approval that regulates them as a cell drug, not the free online tissue registration (which takes only a quick 45 minutes to complete) that they currently have, which regulates them as an acellular product (meaning a product that contains *no live cells*). Despite this, there are some providers promoting their amniotic and cord stem cell therapies via full-page ads and seminars with claims that make them sound like miracle elixirs, not the dead-cell products they actually are.

It’s important to understand that the human body does contain its own stem cells that can be harvested and reinjected by physicians (MDs or DOs) during the same procedure. These bone marrow stem cell therapies for orthopedic applications have over a decade of promising use with supporting literature and patient outcomes data. So if you are considering a stem cell therapy, it’s important that you understand how to separate out the bogus claims made by providers peddling live amniotic and cord stem cell injections. Let’s start by defining amniotic and cord tissue.

Amniotic and Cord Tissues: The Products of a Live Birth

During pregnancy, there are important tissues that support and sustain the baby as it develops and grows. The amniotic sac houses the baby and the amniotic fluid. The placenta attaches to the wall of the sac and circulates nutrients and oxygen to and wastes from the baby via the vein and arteries that run through the umbilical cord. The cord also contains a gel-like substance that supports the veins and arteries called Wharton’s jelly. All of these are products of a live birth, and unless a mother chooses to donate or store any of these tissues after delivery, they are discarded.

There are some stem cells found in two of these tissues during pregnancy and immediately following birth while the tissues are fresh. These are the amniotic fluid (which is mostly baby urine by the time of birth, so few stem cells remain) and the Wharton’s jelly. However, when these tissues are donated for clinical use, the stem cells do not survive the processing required (freezing, storing, shipping, shock-thawing, etc.) to turn the tissues into an amniotic and cord product. In fact, the amniotic and cord products being promoted as stem cell therapies not only contain no living stem cells, but no living cells in general. This leads us into our first bogus claim: simply calling it an amniotic and cord stem cell therapy.

Claim 1: Amniotic and Cord Products Contain Live Stem Cells

By simply calling a procedure a stem cell procedure, the assumption is that the product being injected contains live stem cells. For stem cells to do their job, they must be alive, they must be functional, and they must be healthy. The stem cells in amniotic and cord products are dead! So calling it an amniotic and cord stem cell therapy is misleading at best. We’ve seen a disturbing trend in these clinics even claiming their products contain live cells. The Interventional Orthopedics Foundation (IOF) has tested many of these products and found no living cells, which falls in line with the FDA regulation requiring no living cells. So besides being a bogus claim, this firmly places these products into the category of an illegally marketed drug.

So what do amniotic and cord products have besides dead stem cells? They do have some growth factors and extracellular matrix proteins. However, a platelet rich plasma (PRP) injection contains more growth factors plus it has beneficial platelets and immune cells, and it's far less expensive than an amniotic "stem cell" injection. So if you need an actual stem cell therapy for a musculoskeletal condition, it's imperative that the cells are alive, such as those in a bone marrow stem cell procedure.

Claim 2: Amniotic and Cord Stem Cells Can Regrow a Knee

There is absolutely no stem cell therapy, regardless of the stem cell source, that can regrow a knee or any other joint. When a patient has severely degenerative bone-on-bone arthritis, cartilage can't be regenerated where none is left, yet some of these amniotic and stem cell providers are claiming just that. Stem cells work to repair damaged tissue; they don't create new tissue. In fact, research doesn't really support *any* arthritis treatment, mild or severe, using amniotic or cord products.

Claim 3: Amniotic and Cord Stem Cells Are Supported by Research

To date, there is no extensive published research that supports amniotic or cord stem cells for musculoskeletal conditions, such as joint or ligament injections for any degree or arthritis or other injury. Yet if you attend an amniotic or cord stem cell seminar or question these providers, they are likely to cite or interpret some research that seems to support their product, a common bait-and-switch tactic. At best, they don't understand the research themselves; at worst, they are counting on vulnerable patients to buy their skewed interpretation of the literature. Why? Because the research studies they are providing really have no parallels to the product they are using or the procedure they are performing.

If you are considering a stem cell therapy, regardless of the stem cell source, it's important that the provider give you pertinent research that specifically matches the product, procedure, and body part for your procedure. Patching the covering of the spinal cord with amniotic tissue, for example, may have supporting research, but this isn't the same as an amniotic stem cell injection to treat arthritis of the spine.

Claim 4: Amniotic and Cord Stem Cell Therapies Have Only Successful Outcomes

Any clinic treating patients should be following and reporting its patients' outcomes (functional abilities, pain levels, etc.) as well as the success and failure rates of their procedures. Every procedure ever devised has a success and failure rate, and stem cell therapies are no exception. So a huge red flag should go up if a provider is reporting zero failures on its procedures or says no patient has ever reported a side effect. Providers performing valid stem cell therapies should be utilizing a stem cell registry, such as the one maintained by the IOF, that follows patients at regular intervals, prompting them to report feedback on their post procedure progress.

If an amniotic stem cell provider can cite statistics on their procedures, it is imperative that they can also provide official data to back it up. Again, make sure the information they give you is pertinent to the product they are using and the procedure you are considering. Truthfully, it is highly unlikely that any amniotic or cord stem cell provider would be able to provide any valid outcome data on their procedures since these products are not FDA-approved live-cell products.

Conclusion

The claim of live cells in any amniotic or cord product makes these products an illegally marketed drug. In order to obtain FDA approval even just to call these live stem cell products, each product as well as each indication (e.g., knee injections, shoulder injections, etc.) would require clinical trials costing millions of dollars and taking up to a decade to complete. In addition, the research would need to show that these products do indeed contain live stem cells, which it doesn't. When you see these bogus claims for amniotic and cord stem cell therapies, make sure you stay away from these providers.