

STEM CELLS & AUTISM: ONE YEAR LATER

BY JAMES JEFFREY BRADSTREET, MD, MD(H), FAAFP



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Stem cells remain an unproven but enticing therapeutic option for autism spectrum disorders (ASDs) and other conditions. Regardless of your view of the science or lack thereof, stem cell therapies are being widely practiced around the world. I first wrote about stem cells and autism for this journal one year ago.¹ With what I have since learned, looking back at what I wrote then reinforces that my thinking about stem cell therapies was reasonable. In addition, the past year's first-hand journey with these therapies has brought forth some important new observations. Stem cells were a therapeutic option I felt was worth trying for my own sports-related injuries and for my stepson's autism. Although my choices don't validate stem cell therapies, receiving them personally has given me a real-world perspective.

The most significant change in my thinking related to stem cell therapy has to do with specific cell choices. Although this is a complex, controversial, and challenging topic, a discussion about cell choices is important for evaluating what is currently happening in many places outside the US. We also need to consider how effective this therapy might be for autism. I will be frank in this discussion, but at the same time I hope I don't come across as insensitive to anyone's beliefs or ethics. I have great respect for human life and have dedicated my career to helping people enjoy a high quality of life. After years of studying stem cells, I believe they hold great promise as healers of what would otherwise be considered untreatable disorders.

TYPES OF STEM CELLS

Let's rewind our discussion back to the point where we learn about what a stem cell is, and then, let's explore what types of stem cells are being researched and used. First, stem cells must possess *both* the capacity to reproduce themselves and the potential to change into specialized cells. As an example, a neuronal stem cell must be able to make other stem cells and then ultimately turn into a neuron (brain cell) itself.²

There are five types of stem cells: embryonic stem cells, fetal stem cells, adult stem cells, induced pluripotent stem cells, and designer stem cells, each of which is defined in the paragraphs that follow.

Embryonic stem cells (ESCs): ESCs are derived from the very early stage of the growing embryo (around 50-150 cell stage) (see Figure 1). These cells are pluripotent (the most potent apart from a fertilized egg); however, of all the stem cell types, these are the most difficult to regulate and control. They show particular promise in spinal cord injury and retinal degeneration.

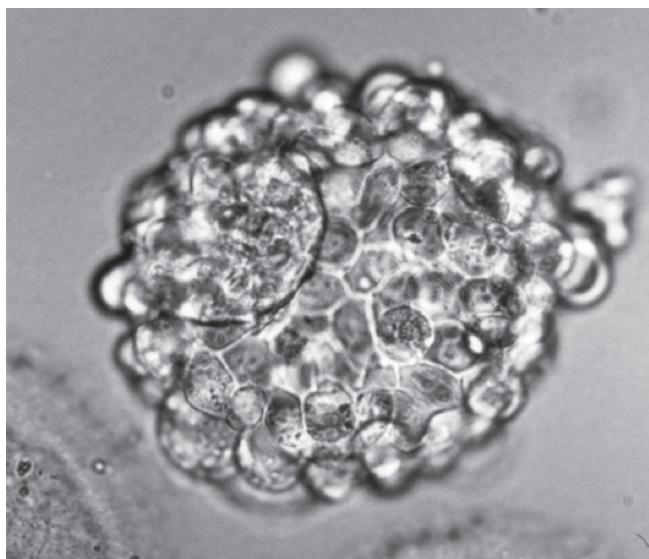
ESCs are the byproduct of infertility treatments and result when a greater number of fertilized eggs (turned embryos) are created than can be used by the mother. If the unused embryos are donated for medical use or research, they can be used in special studies. Because each of these cells is capable of producing a human being, they are ethically complex and controversial. Their use, therefore, is highly regulated. Few countries allow therapies with ESCs apart from legally regulated medical research, and many countries won't permit research on ESCs

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in any form. There are a few ongoing US studies using ESCs in spinal cord injuries and other serious disorders, but because there isn't a large supply of these earliest human stem cells at this time, they are not in significant use in medical therapies anywhere in the world. For the purposes of this article, we can leave ESCs out of our remaining discussion since they are not, to my knowledge, being used by any clinic in any country to treat autism.

Fetal stem cells (FSCs): As the blastocyst grows in the womb, it creates three distinct germinal layers, which will ultimately become different structures in the fetus. FSCs can be derived from any of these three germ layers (ectoderm, mesoderm, or endoderm). Because FSCs are already committed to one of the three semi-specialized cell lines, they have less potential than the pluripotent (undifferentiated) ESCs. FSCs are, however, more potent than adult stem cells.

Figure 1. Human embryo at the blastocyst stage



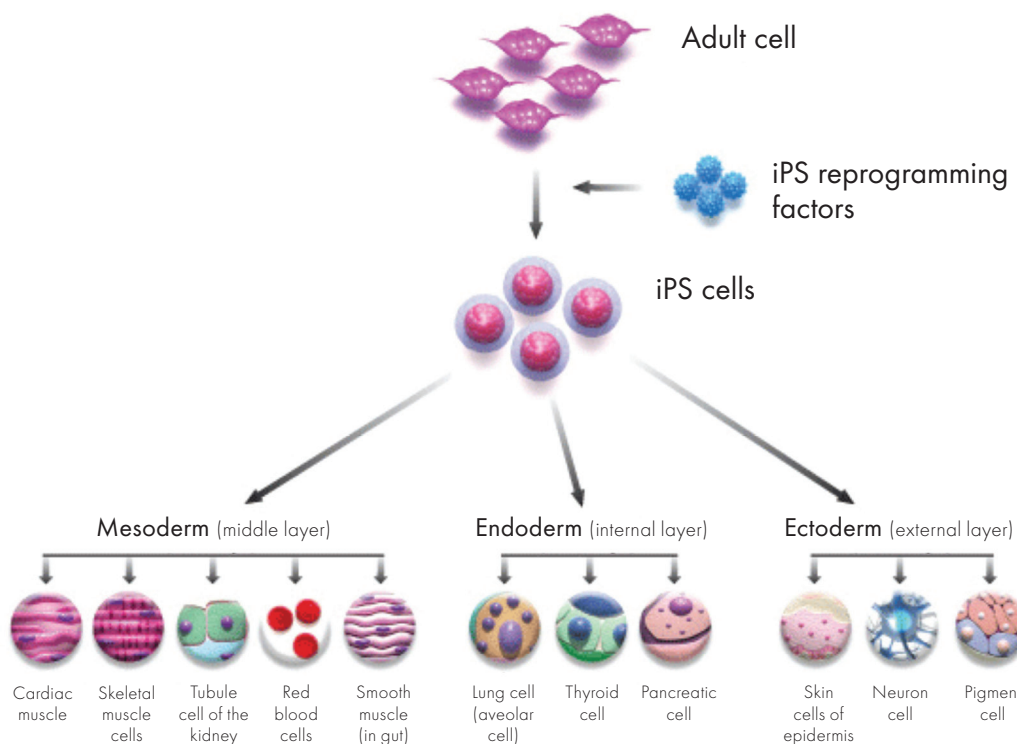
Source: <http://archive.eurostemcell.org/images/StemCell/Human-blastocyst.gif>

Adult stem cells (ASCs):³ ASCs, by definition, must express several particular surface antigens and (absent lab manipulation) are less potent than other stem cells. There are many types of ASCs, but in practice we are limited at this time to mesenchymal stem cells (MSCs) from adipose tissue, bone marrow, or the umbilical cord (Wharton's jelly-derived MSCs, also known as WJMSCs). Umbilical cord blood has hematopoietic-related (blood-related) stem cells, but these do not have neuroprogenitor or MSC potential without laboratory manipulation.

Induced pluripotent stem cells (iPSCs): Somewhere between the native MSCs and the next type of stem cell (designer stem cells) lies the laboratory induction of specific stem cell types but without genetic (designer) manipulations. These cells come from adult cells, but they are induced with chemical signals to convert to specific cell types such as neuronal cells. These adult MSCs also can be converted into pluripotent cells just as though they were embryonic stem cells (see Figure 2).

Designer stem cells: These are specialized stem cells created via biochemical manipulation of some other cell (generally an ASC or WJMSC). Biotechnology companies are hoping to cash in in a big way on these types of cells since they have the potential to be patented.⁴ Already being used in research, I think we will see the vast majority of future research geared toward this type of cell—not because it is necessarily better—but because it is vastly more profitable. Presently, however, designer stem cells are not on the market.

Figure 2. Induced pluripotent stem cell (iPSC) pathway



Source: <http://www.sigmaldrich.com/life-science/stem-cell-biology/ipsc.html>

USE OF FETAL STEM CELLS

FSCs are derived from elective abortions, generally those performed prior to 12 weeks gestation. FSCs derived at older gestational ages (after 12 to 16 weeks) express a more adult pattern of cell surface antigens and are more rapidly rejected by the new host. This makes them less suited for clinical treatments.

Obviously, use of FSCs raises some critical questions, including questions about how stem cell clinics get access to these cells and about legality, ethics, and safety. In many countries, there are no specific laws governing the unmodified use of fetal stem cell transplants for medical applications apart from the rules already on the books regarding human blood or organ donation and use. By *unmodified*, I mean that the cells have not been treated chemically to alter their characteristics. Thus, in the same way that doctors can transplant a cornea to correct a vision impairment, they can, in theory, transplant FSCs to treat anything agreed upon by patient and doctor. In actuality, however, it is far more complicated than that in most countries. To my knowledge, fetal tissue use in the US is limited to research conducted by universities and biotechnology companies. More specifically, this means that FSCs are not being used in US medical clinics to treat patients. The research being conducted on natural (as opposed to enhanced) FSCs is limited not just in the US but also in Canada, the United Kingdom and other member countries of the European Union, Australia, New Zealand, and South Africa. To date, I have not been able to find any specific information about Japan's use of fetal tissues in medical clinics.

FDA GUIDELINES

In 2006, the US Food and Drug Administration (FDA) issued updated and revised guidelines for stem cell therapies. Unfortunately, the revisions only further confused many people's understanding of the FDA's intent. In the 2006 update, the FDA extended its authority to medical practice previously regulated exclusively by state medical boards and hospital ethics and therapeutics committees. The FDA did this by expanding its authority under sections 351 and 361 of the Public Health Safety (PHS) Act. More specifically, the update added a discussion of the FDA's authority to regulate stem cells when they are used for something other than their *normal* function. Not surprisingly, a debate immediately ensued as to what defines the normal function of a stem cell. Discussion then quickly progressed to the currently heated debate about reimplanting stem cells derived from self-donation (i.e., harvesting one's own bone marrow or fat) and the controversy of transplantation from donors. (Regarding the latter, there is agreement that transplantation of stem cells from donors must meet the transplantation criteria of section 361 of the PHS Act, just as with any other organ or blood donation).⁵

While there is clear agreement that the FDA has no authority over the individual practice of medicine by doctors, in the 2006 update, the FDA seemed to say that it has control over what doctors do with stem cells. That statement represents a completely new area of federal authority over the practice of medicine. Up until that point, US doctors had been exclusively regulated by state medical boards (and were also subject to the legal authority of agencies such as the Drug Enforcement Administration). Unfortunately, however, as the example of stem cells illustrates, medical practices have advanced faster than state and national legislatures' capacity to pass regulatory guidance.

To this day, it remains unclear whether a stem cell that has not been manipulated biologically and which retains its natural properties is further subject to the jurisdiction of the FDA for its intended medical application. With this continued lack of clarity, issues surrounding the use of FSCs have gotten more and more complicated. Many years ago, through a process of complex and lengthy litigation against the agency, the FDA lost its ability to regulate the off-label use of medicines by doctors and consumers. An

outcome is that, in general, the FDA does not regulate surgical procedures or guidelines but does regulate surgical hardware such as artificial joints. In my mind, this victory allowing off-label use to be at the discretion of the physician remains a cornerstone of healthcare freedom. The FDA does restrict the manufacturers of medicines and other products from *promoting* their products for off-label use. But stem cells are human cells or tissues, not medicines; only when they are manipulated should the FDA consider them a biological agent and have jurisdiction over their use. At any rate, because the FDA's jurisdictional reach remains blurry, many doctors have elected to pursue stem cell therapies in foreign (offshore) jurisdictions with more straightforward regulatory environments.

We will talk more about these issues in a bit, but for now I want to continue discussing FSCs. In the US, the topic is presently a non-issue. There are no guidelines for donation or sale of aborted fetal tissue, and I can only imagine the uproar that "selling" aborted fetuses would create. Nonetheless, fetal stem cell research and therapies are a reality in other countries, including Russia, Ukraine, and China. I happen to know a good deal about FSC-related work in Ukraine (though I know less about FSCs in Russia and China). Ukraine gained its independence from the Soviet Union when the latter dissolved in 1991. Shortly after that, EmCell started as a public-private joint venture in Kiev, based on the pioneering work of Professor A.I. Smikodub from the National Medical University of Ukraine. The team created by Professor Smikodub was the first to describe and publish outcomes from treatments using FSCs for a range of disorders, including AIDS (HIV infection), types 1 and 2 diabetes mellitus, aplastic anemia, psoriasis, rheumatoid arthritis, degenerative diseases of the nervous system, Crohn's disease, ulcerative colitis, bowel cancer, and several other disorders. While this group's work is largely unknown, unrecognized, and even ignored in the US (perhaps due to its publication in Russian and Ukraine languages), the group's pioneering role is undeniable.⁶

Smikodub and colleagues started their work in the late 1980s even prior to the dissolution of the Soviet Union, and they have more combined therapeutic stem cell experience than any center in the world. Reportedly, over 7000 patients have received FSCs at EmCell in Kiev, with no reported infections or significant complications. Although EmCell's track record of no side effects offers room for optimism, randomized controlled trials are lacking as are English translations of EmCell's pioneering work (a gap that I am working on rectifying). Over the next few years, I anticipate that more objective data will emerge from the work at EmCell.

WHAT MAY STEM CELLS OFFER FOR THE TREATMENT OF AUTISM?

Autism is a complex developmental neurological disorder that appears to manifest as immunological dysregulation of special neuroimmune cells (glia), with resultant disruption of brain organization.⁷ On the surface, disruption of brain organization would seem to imply that the condition is irreparable. However, new evidence indicates that, at least in some cases, the immune disruption may be inhibitory as opposed to destructive, leaving room for hope that the effects may be reversible.⁸

That being said, let us revisit the previous discussions pertaining to fetal and mesenchymal stem cells. FSCs are the substance of human life—all that you are today comes from your FSCs. MSCs are the biological force behind repair and immune regulation. MSCs produce the chemistry to induce repair in recipient organ systems and to regulate the host's immune system.⁹

The human brain—particularly the developing human brain—is the most complex structure in nature. With its numerous dendritic connections and exceptional processing speed, the human brain rivals the best supercomputers. Repairing such an intricate organ is a daunting and overwhelmingly difficult task, which is why many consider autism to be incurable. By natural design, however, the purpose of stem cells in the brain

By natural design, the purpose of stem cells in the brain is regulation, healing, and repair. Biologically, therefore, stem cells appear to be better suited to heal the brain than any other current therapy. No matter how challenging the task of repairing the brain may appear to be, case reports have built an argument for supporting the reversibility of autism using immunological interventions.

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No matter how challenging the task of repairing the brain may appear to be, case reports have built an argument for supporting the reversibility of autism using immunological interventions.^{11,12} Additionally, another totally different approach, applied behavior analysis (ABA), has also achieved documented reversals of IQ loss and behavioral abnormalities in up to 50% of children with autism.¹³ Regardless of what happens in the brain as a result of ABA, its success at least speaks to the fact that a large subset of children has reparable brain syndromes. This is not the place to elaborate on the potential biochemical and neurotransmitter changes resulting from ABA, but I would speculate that it increases acetylcholine and reduces dopamine and that this combination reduces oxidative stress and inflammation.

Cerebral palsy (CP), like autism, is also considered an incurable brain syndrome. CP is thought to be the result of perinatal hypoxic injury to the brain,¹⁴ and until recently there was no effective therapy. Some impressive news reports¹⁵ about an autologous (self-donated) umbilical stem cell therapy study at Duke University (not yet published) as well as the first published case reports from two children treated in Thailand¹⁶ both document this type of FSC treatment. Both children in the latter study showed rapid improvement in gross motor scores with no apparent side effects. The responses seemed to occur too rapidly to be due to actual neurological reconstitution from engrafting of the umbilical stem cells. Instead, the therapeutic results are more likely due to the production of cell mediators by the stem cells and the change in neurological dysregulation that followed.



Source: http://blogs.e-rockford.com/applesauce/files/2011/11/stemcell-research_1532389c.jpg

Intravenous immunoglobulin (IVIG) therapy represents another relevant example of how a therapeutic treatment can modify immune responses. In the mid-1990s, Professor Sudhir Gupta from the University of California-Irvine published a case series of children with autism whom he treated with human IVIG.¹⁷ Some of the children responded dramatically, quickly, and positively to the intervention. Professor Gupta has continued to use this therapy for children with autism as have I. Sometimes it is amazing how

rapidly IVIG helps alleviate the symptoms of autism. In at least this subset of rapid responders, it has been theorized that IVIG removes an immunological inhibitor. As with the umbilical stem cell therapy results in Thailand, the restoration of function with IVIG occurs too rapidly to be due to neuronal regeneration and synaptic development.

In other children with autism and fragile X syndrome, the use of anti-inflammatories such as steroids,¹⁸ spironolactone,¹⁹ pioglitazone,¹² and minocycline²⁰ has also resulted in rapid improvements. In a single case report, an older individual not formally diagnosed with autism but clearly on the autism spectrum responded rapidly to the anti-TNF-alpha drug entanercept (Enbrel®).²¹ TNF-alpha is a powerful mediator of inflammation and a target for many specific anti-inflammatory medications.

Returning the focus to the stem cell discussion, stem cells offer a potentially self-renewing source of immunological regulation to the body and brain. They also offer a wide array of biochemically mediated cell signals to induce repair. In autism, many body systems could benefit from this process of healing signals from stem cells. The potential options and benefits are numerous, as illustrated by a few examples:

- In autism, it has been postulated that the blood-brain barrier (endothelium) does not function normally²² and that autoantibodies to the endovasculture are commonly found.²³ As shown in Figure 3, the blood-brain barrier defines the environmental separation between the brain and the rest of the body. If the blood-brain barrier is chronically inflamed, abnormal function of the brain would be expected. Stem cells may, more properly than medications, regulate the immune system in the brain and provide a stable, more functional environment.
- Chronic inflammatory changes are noted in the intestinal tract of a significant subset of children with autism.²⁴ Other forms of inflammatory bowel disease have been responsive to stem cell therapies.²⁵

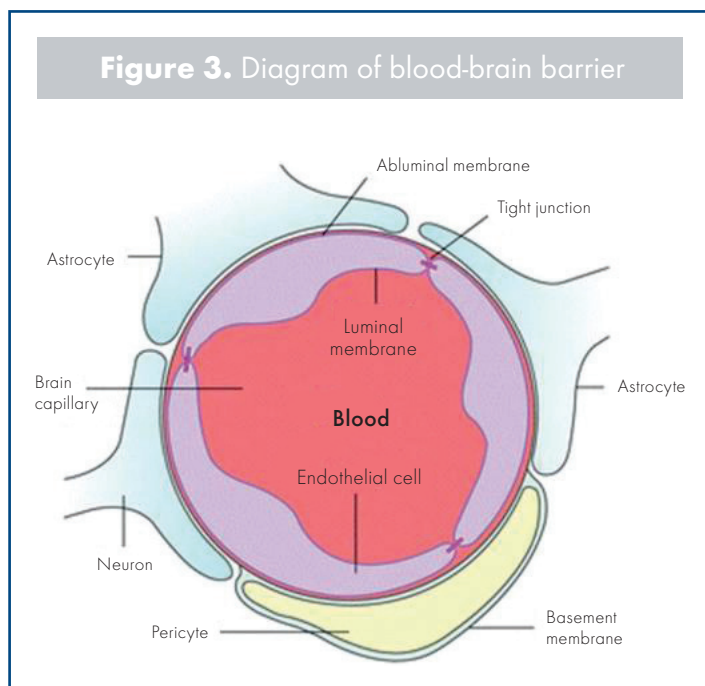
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- Similar to cerebral palsy but on a lesser scale, many children with autism demonstrate motor dysregulation and dyspraxia.²⁶ This includes abnormal proprioception, abnormal gross and fine motor control, and cross-extensor reflex abnormalities. Early positive observations demonstrated by stem cell interventions for treating CP suggest that motor planning issues in patients with autism may respond in a similar manner.
- Lastly and hopefully, stem cells may provide repair and replacement neurons over a long period of time to restore deficient function.²⁷ Although this remains an uncertainty, preclinical observations in animals suggest that, in theory, it is at least a potential outcome.²⁸



Stem cells being infused at EmCell.

Figure 3. Diagram of blood-brain barrier



Source: http://media.tumblr.com/tumblr_lk7odmeeCu1qc9f5v.jpg

ANECDOTAL OBSERVATIONS OF STEM CELLS IN AUTISM

I maintain a blog where I strive to discuss a wide variety of health issues. Autism and stem cells, however, seem to take up most of our discussions. Through this forum, I have been attempting to follow the stem cell therapy outcomes (three of which I include below) from patients in my practice. (I have several more, but space does not suffice to include them.) The three following patients were all treated at EmCell, which uses fetal stem cells. Generally, the outcomes were about the same in each case. Behavioral changes seem to occur first and are often dramatic. Language is more challenging, although most children are experiencing some gains in both receptive and expressive language.

A mom from Canada sent me this post about her two boys and their responses to stem cells:

Dr. Bradstreet, I am so glad you are in Kiev learning about what EmCell is all about. I went to EmCell July 2011. I have to say our experience was very good. Our kids 7 and 8 with autism are getting better every day. K could not be in school full-time before we went to EmCell, now he goes to school full-time and is doing well. K can also read now, he talks in full sentences, asks questions and answers questions. It is just amazing how much our lives have changed since we went to EmCell. J and K are much happier. I think their quality of life is much better. It is nice to be able to chat with our kid now.

These parents from Dubai posted the following account to the blog:

Our 7-year-old boy has been going through major changes since the stem cell treatment at the end of November (EmCell). Within three weeks he added and retained seven words to his vocabulary, which is quite a feat considering he has only spoken and retained seven words in as many years. Because of his verbal dyspraxia, he has spoken more words over the years, but would lose them immediately. We have also realized that he no longer pronounces the end sound of a word first, which was a constant prior to the therapy. He is blending multiple sounds moving towards proper pronunciation, something he greatly struggled with. In fact, the first multiple sound word he added was in the taxi ride home from the airport after returning from Kiev. He saw the petrol station with a car wash and suddenly pointed and said "wash."

The last week or so his verbal growth has reached a plateau for the time being but major changes are still ongoing as he is obviously very displaced within himself, but in a positive sense. Lots of sensations going on in his mouth, his distended belly is now flat and almost defined, and has three regular [bowel] movements a day. He seems to have found a new store of energy as he is more hyper than usual and we have a lot more stim running, but this has always been the norm when he goes through growth spurts and another confirmation that a lot of change is going on inside his little body.

His teacher and therapists all comment on the changes, not just verbally, but also on his attention and willingness to participate in activities, even when he obviously cannot be bothered. There is an obvious correlation between the decline of his listening and participation skills when he is experiencing major changes within himself, but within a week or so he is back on form plus some.

Parental observations are anecdotal and not equal to rigorous scientific investigations, but they are important to document at this early stage of therapeutic application. This next parent account is particularly detailed and seemingly objective. The account pertains to a girl who had been largely static with language and other developments over the past year. The girl was 4 years old at the time of treatment.

We just hit the three-month mark and I wanted to touch down and let you know how she is doing these days after EmCell therapies. She's actually doing pretty good! Our ABA supervisor sent me an e-mail with some changes they've noted in the past 3 months. I didn't tell them about the stem cell treatment so I think their observations are pretty unbiased. We've also noticed that her PANDAS symptoms seem to be almost completely gone since the stem cell [therapy]. Anyway, here are some changes we've noted in the past 3 months. Most of these are new changes that her therapists have brought up so I feel good knowing that I'm not "imagining" anything.

1. Significant decrease in rigidity, decreased obsessive-compulsive behaviors, and anxiety.
2. Increase in the following: attending, language comprehension, motor imitation skills, visual discrimination, and understanding of concepts.
3. Increase in her ability to tolerate changes and is more easily directed/redirected.
4. She understands the power of language and team has seen an increase in communicative intent and understands the back and forth of language.
5. She looks forward to her ABA sessions and has developed positive relationships with the therapists.
6. She is showing interest in other children and seems to want to play but doesn't know how to initiate (previously uninterested in other kids).
7. She is interacting more with her brother.
8. She's showing much more affection to family and friends.
9. She's dropped vanco [vancomycin], zithro [azithromycin], and nystatin completely and cut clonidine and omeprazole doses in half with no regression.
10. Increase in verbal attempts, but still very lacking in expressive language changes.

Recently, I have had several patients treated at clinics other than EmCell. One clinic (located in the Dominican Republic) uses a combination of bone marrow MSCs and adipose-derived MSCs. MSCs are highly counter-regulatory to the immune system,²⁹ downregulating inflammation and promoting healing. However, there is an intrinsic problem with adipose-derived MSC therapy. Because the adipose tissue is surgically removed from the patient using liposuction, the process creates a wound. Stem cells naturally seek out areas of

damage; as a result, they would be expected to return to the wound site. In an attempt to minimize that problem, the clinic banks the cells for 7 to 10 days before reinfusing the stem cells. Because it is doubtful that even 10 days are adequate to heal the surgery site, it is difficult to know what proportion of the stem cells later make it to the sites where we would want them to go to address symptoms associated with autism. Despite this shortcoming, these patients have reported some positive gains, including reduced self-stimulatory behaviors, improved mood in some cases, and decreased gut issues in one child. So far, in the procedure involving bone marrow and adipose-derived MSCs in combination, these patients haven't reported any language gains or other changes.

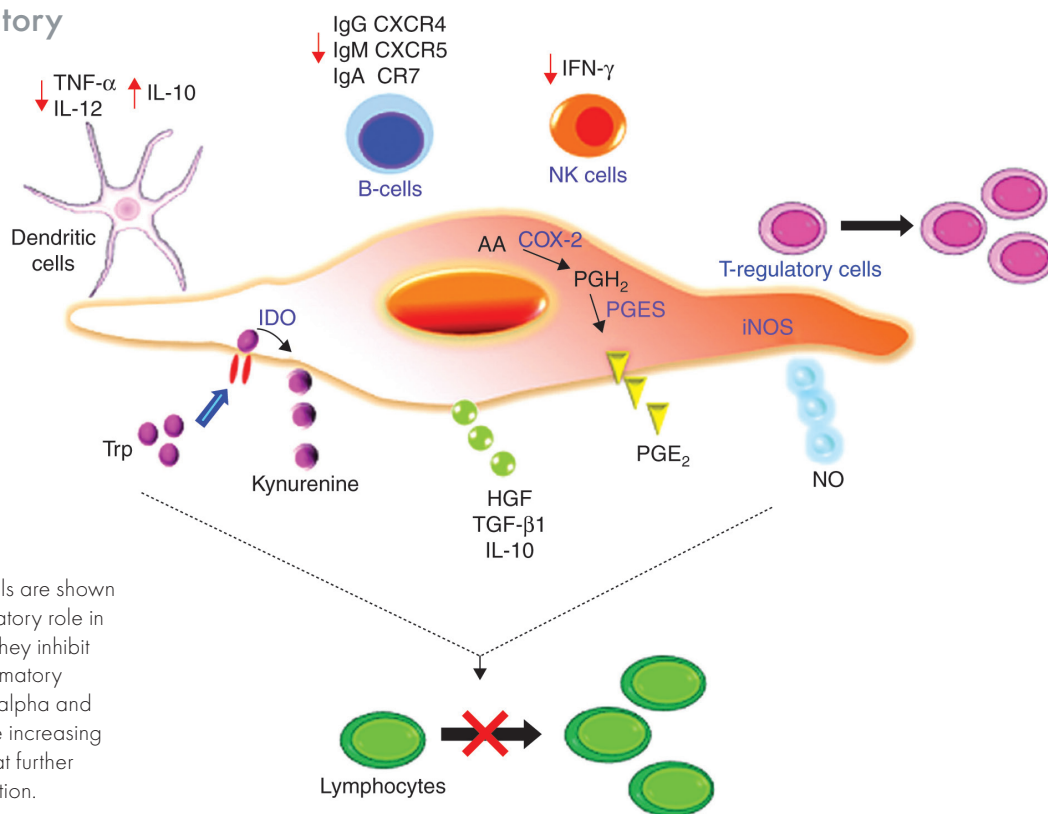
Several other children who are my patients were treated at a Panamanian center that apparently uses pooled or expanded umbilical stem cells. A paper published by this group suggests that indeed they are using expanded cord blood rather than WJ-related mesenchymal stem cells.³⁰ These expanded stem cells are adult-type and, depending on the techniques used, they would be expected to express HLA type II surface antigens.³¹ What this means is that their longevity in the body is most likely going to be short due to their rejection by the recipient's immune system. This type of cell (while present) is anti-inflammatory; in the children with ASDs treated at the Panama clinic, this has sometimes equated to short-term gains, but no sustained benefits have been observed. I am aware of one child with CP who, at age 3, was treated at the Panama clinic and showed very significant improvement in spasticity and motor control. This effect has been sustained for greater than 6 months.

CELL CHOICES: MSCs

Before concluding, I want to return the discussion to adult MSCs. Mesenchymal stem cells are derived from the fetal mesodermal layer. They

Figure 4. Mesenchymal stem cells

Immunomodulatory



In this diagram, stem cells are shown to exert an anti-inflammatory role in the local environment. They inhibit the production of inflammatory mediators such as TNF-alpha and interferon gamma, while increasing the T-regulatory cells that further downregulate inflammation.

Source: Iyer SS, Rojas M. Anti-inflammatory effects of mesenchymal stem cells: novel concept for future therapies. *Expert Opin Biol Ther.* 2008 May;8(5):569-81.

In autism, without further transformation, MSCs would be expected to have a peripheral anti-inflammatory effect, with the potential to heal the gut and quiet autoimmune reactions.

are hardy and plentiful in both bone marrow and fat. Beyond their ability to create bone, connective tissue, cartilage, and adipose, they are strongly anti-inflammatory. In the laboratory, MSCs can also be biologically transformed to become other cell lines, including neuronal. For this reason, I expect that in the future these types of cells will be the resource for a variety of designer stem cells.³² In autism, without further transformation, MSCs would be expected to have a peripheral anti-inflammatory effect, with the potential to heal the gut and quiet autoimmune reactions. It would be doubtful that they would directly convert to neurons and more likely that they would signal repair in the brain with their intrinsic cellular chemistry.³³

POTENTIAL RISKS

We must also ask if there are any significant potential risks associated with using stem cell therapies for the treatment of autism. This is a complex area because of the various protocols, multiple cell sources, and different cell types presented in the medical literature. First, it is helpful to note that we are not dealing with the more complicated graft versus host type of reactions. For example, unlike bone marrow transplants after chemotherapy for leukemia, where rejection is a potential issue, a person with autism has an intact immune system to prevent graft versus host reactions.

Although increased cancer risk for patients treated with both self-donated (autologous) and donor (allogeneic) stem cells has been suggested to be a potential issue by some authors,³⁴ the doctors at EmCell claim that no cancers have thus far been reported after treatments involving up to 20 years of follow-up. In fact, EmCell doctors have clinical observations indicating just the opposite, namely a reduction in cancer-related issues after stem cell therapy. The cancer risks appear to be limited to patients with prior chemotherapy for lymphoma and leukemia or in stem cells derived from induced pluripotent cells.³⁵ Most of the long-term observations related to cancer are in populations where ongoing anti-rejection drugs are being given, and in that population, a significant increase in cancer risk is observed. The issues that are associated with those scenarios don't apply to treating children with autism. In theory, ESCs would seem to have the greatest risk of cancer, although so little work has been done with these cells that it is hard to evaluate. One child who appeared to have ESCs injected into his spine for an unusual and fatal genetic disease developed benign tumors within the spinal canal that required decompression surgery.³⁶ While some protocols for ASD and CP utilize the injection of stem cells into the spine, I strongly encourage patients NOT to allow this procedure.

Infection transmission from contamination of the stem cell source is also a risk. A recent evaluation of cord blood samples by the American Association of Blood Banks showed that vaginal delivery significantly increased the risk of bacterial contamination of the cord (logical) and that the rate of bacterial

contamination was at least 4 percent.³⁷ By using blood donation standards for any form of allogeneic transplantation, a recent review placed the risk of finding a contaminated specimen at the time of screening at about 0.5 percent but estimated post-screening contamination at close to zero for all the agents tested using modern screening techniques.³⁸ This type of conclusion raises the concern that not all infectious agents can be practically screened for, though current screening techniques encompass all major and common disorders. Freedom from contamination, therefore, depends largely on the quality of the screening technique and the pedigree (source documentation) of the stem cells. Consumers should ask for and expect certification of the sample's bacteriological (especially cord blood) and viral testing. Consumers should also know where the material to be transplanted was sourced and what recordkeeping is maintained by the transplantation facility.

Beyond this, I am additionally concerned that cultured (amplified) stem cells grown in the lab could test clean from the source but then subsequently be subject to additional laboratory contamination. I know with certainty that there is a potential for all labs to be subject to cell culture contamination; this is attested to by the recent recalls of flu vaccine in New York.³⁹ In my review of the medical literature, apart from umbilical cord blood testing, I could find no published reports estimating contamination of lab-grown stem cells.

CONCLUSION

Where does all of this leave us? If I put on my hat as a father of a child and stepchild with autism (yes, I have two boys in my life with autism), I am left with this sense: if the risks are reasonable and the finances allow it, I want to try everything that has the potential to improve my boys' health. As a physician, I have read hundreds of research papers on stem cells and their potential to heal as well as their unknown potential to do harm. All of the available choices have challenges. Self-donated umbilical stem cells would be first on my list for use with autism, but as of yet I have no experience with any child with autism receiving their own umbilical stem cells. Next, I would select fetal stem cells because of their potency. If considering autologous stem cells, the potential flaw associated with using autologous cells is the source of the cells: they are from a child with autism who is known to be genetically susceptible. In other words, whatever autism is, the stem cells of the autistic child did not prevent the autism from happening in the first place. That might mean that autologous stem cells lack the therapeutic capacity to heal the existing autistic state, yet this question still remains to be answered. Finally, another option is donated umbilical stem cells, which are potent, but as discussed, their survivability is most likely short. In the end, when weighing all these considerations, the complex decision of whether or not to use stem cells can only be made by us as parents.

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Ready to Try Enzymes?

5 Tips to Get You Started

- 1 Match the enzyme to the food it breaks down
- 2 Take enzymes near the beginning of each meal
- 3 Dose based on the size of the meal
- 4 Use products formulated by a PhD biochemist
- 5 Learn more about enzymes at houston-enzymes.com



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PhD Biochemist,
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