

# The Next “Boom” for the Baby Boomers: Interventional Regenerative Orthopedic Medicine



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## INTRODUCTION

The baby boomer generation is one of the largest to ever exist in the United States. They grew up in a time of significant change in both politics and culture, and have had the most significant socio-economic impact in US history. The “baby boomers” were born between 1946 and 1964 and now represent over 75 million people. They have had an unprecedented economic impact, pushing up rates of homeownership, consumer spending, employment, and healthcare. They are currently the most significant force operating on our healthcare system.

In addition, the baby boomers lead an unprecedented fitness revolution. Kenneth H. Cooper, M.D.’s 1968 best-seller *Aerobics* put the age of modern exercise on the map. Back then, less than 24% of American adults exercised regularly. By 1984, that figure rose to 59%. Cholesterol and blood pressure levels fell. Deaths from heart disease were reduced to 48%. This was in large part due to changes in attitude and the baby boomer generation’s adoption of health and fitness behavior. Over the course of

the last 20 years, the baby boomer population's focus on health and fitness has made a significant impact on exercise and nutrition. They have adopted a wellness model that has led to a number of changes in healthcare goods and services. Physicians and medical care institutions are rapidly having to make adaptations to meet the healthcare and social needs of this population.

## **THE NEED FOR INTEGRATION**

Baby boomers have altered the socio-economic landscape with concepts such as “active retirement.” They have reengineered life. They often want quick fixes that require little change and instant improvement. We have seen the explosion of antiaging medicine (now called “age management” medicine.) They have also “broken the mold of what 50 looks like.”<sup>1</sup> The term “integration” is a key concept for this population and for companies or services providing for this population. Physicians and surgeons have been historically slow to accept the concepts of fully “integrative” healthcare services. Although we have seen a trend towards integrative medicine and acceptance of alternative healthcare practitioners, the medical industry as a whole has been slow to accept these models. Yet, those physicians and surgeons who have developed an “integrative model” have enjoyed significant success in fulfilling the demands of the baby boomer population.

## **THE NEXT BIG THING FOR THE BABY BOOMERS**

With the social, economic, health, and wellness success of the baby boomers, individuals are living longer and with better overall quality of life, health, and wellness. It is common to see individuals from this generation with very few medical problems except for orthopedic and musculoskeletal conditions. Every day we see patients with very few cardiovascular, pulmonary, and other systemic diseases who are nonetheless hampered by chronic pain and physical disabilities associated with degenerative joint disease and injuries to aging tendons, ligaments, and cartilage. For many baby boomers the only thing that slows them down is this orthopedic disability. Although total joint replacement surgery has been a revolution for this generation, the majority are seeking nonoperative options for care. Many of them have exhausted the alternatives: physical therapy, osteopathic manual therapy, chiropractic, acupuncture, naturopathic medications, and other treatment, only to remain frustrated with persistent pain and disability. Traditional orthopedic surgery offers few nonoperative management choices. The disciplines of physical medicine, rehabilitation, and sports medicine have also been slow to provide options aside from their traditional methods, which are insufficient in addressing these types of problems. This has created a need for a new subspecialty in medicine, that is, the need for advanced medical practitioners utilizing *interventional regenerative orthopedic medicine*.

One phenomenon in medicine today is the rise of stem cell therapies. Unfortunately, the utilization of stem cell therapy has risen faster than the evidence to support its use. In all of the disciplines currently exploring the use of stem cell therapies, the orthopedic application of regenerative and stem cell therapies is one of the most complex. We have been working with regenerative medicine techniques applied to orthopedic conditions for over 27 years. We have explored and integrated a myriad of regenerative medicine techniques over the last three decades, trying to improve nonoperative treatment

options for patients with orthopedic and musculoskeletal injuries and disease. While many were critical of the “investigational” techniques we utilized, we stayed the course and went on to help develop this field of medicine.

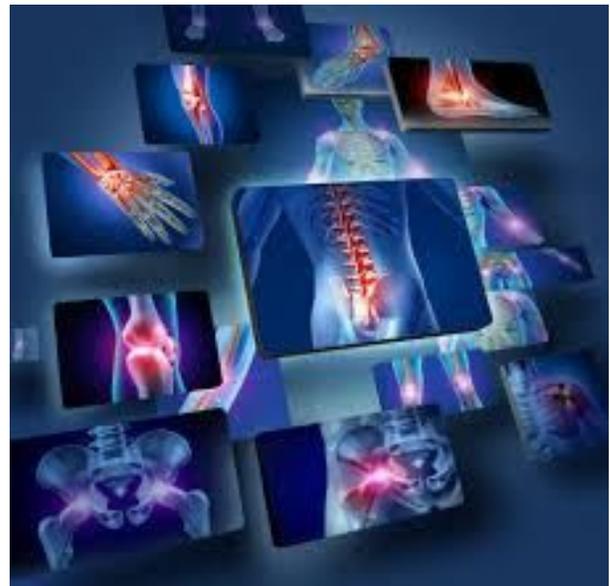
One of the most important lessons that we have learned is to make use of integration. After several decades of working diligently in research and development, we came to realize that the science and technology of regenerative medicine is moving much too fast for a single entity to keep up. For that reason we developed six centers of excellence around the USA, forging relationships with some of the most innovative orthopedic, pain, sports medicine, stem cell, and regenerative medicine specialists in the country. It is through the establishment of these relationships that true integration of basic cell biology, stem cell, regenerative medicine science, and musculoskeletal orthopedic medicine has been realized. Now, as a team of physicians across the US, we are able to develop consensus guidelines and advance the technology being utilizing today.

Our vision was to create centers that bring together top physicians, coordinating their care with consensus about treatment protocols, research, and technology development. These efforts have been successful in developing a new hybrid medical subspecialty, which has been nicknamed “Interventional Regenerative Orthopedic Medicine” (IROM). IROM physicians practicing in this area are specialized in interventional, non-operative, minimally-invasive orthopedic procedures. Some have called them “interventional orthopedists.” Typically, they are not orthopedic surgeons but rather interventional spine and pain medicine specialists with additional unique subspecialty training.

## **WHAT ARE INTERVENTIONAL REGENERATIVE ORTHOPEDIC MEDICINE SPECIALISTS?**

This discipline of medicine is a rather new field. There are no residency programs or traditional medical training programs in it to date. There are no accredited fellowship training programs available for training in this area either. This leads to a wide disparity of expertise and training.

The field is dominated mainly by physical medicine and rehabilitation physicians who have completed a residency program in physical medicine and gone on to complete a subspecialty fellowship in pain medicine. This provides a double-boarded physician who is now at least prepared to begin training in orthopedic medicine (which can take 5-6 more years.) It requires advanced ultrasonography as well as advanced spine intervention skills.



These physicians have abandoned the traditional use of surgical and ablative technologies, replacing them with techniques utilizing regenerative medicine principles (as will be described below.) One of the frustrations of this new discipline is the increasing number of physicians jumping into stem cell therapies without foundational and fundamental knowledge and experience utilizing even some of the



most basic regenerative medicine techniques. These providers lack the training and experience that is necessary to progress through the ranks and prepare themselves technically to make clinical decisions utilizing stem cells and other modern, regenerative medicine techniques.

Many problems do not require stem cell therapies and can be treated with more simplistic regenerative medicine interventional procedures. This saves both time and resources. We are seeing anesthesiologists, pain physicians, sports medicine doctors, as well as orthopedic surgeons take an interest in this field.

The interventional regenerative orthopedic medicine practitioner needs to have a comprehensive background in manual medicine, alternative medicine, biomechanics, rehabilitation, sports medicine, diagnostic and interventional ultrasonography, and advanced, image-guided procedure skills to make appropriate decisions in regards to using stem cell and

regenerative medicine technology as applied to a specific disease or injury.

## **COMMON CONDITIONS IN BABY BOOMERS THAT CAN BE TREATED BY THESE PROVIDERS**

Through diligence in maintaining healthy diet, exercise, and lifestyle, many individuals in the baby boomer population have reduced risk factors and improved their overall state of health. The pulmonary, cardiovascular, and muscular system improves with exercise. Muscular strength, agility, and flexibility also improves with exercise. The problem this generation must contend with is the effect physical activity and injury have on the supportive ligaments, cartilage, intervertebral discs, and soft tissues that support the joints. This is the baby boomers' Achilles heel.

For example, the muscles of the shoulder can be strengthened with exercise, and range of motion can be improved with stretching. However, the rotator cuff tendons can gradually wear, thus developing degenerative changes that, ultimately, can lead to partial thickness tears and tendinopathy. This can cause chronic pain. These degenerative and traumatic tendon injuries have a poor potential for healing compared to muscular injuries and other soft tissue injuries. These patients often deal with chronic shoulder pain and reduced function despite months, or even years, of physical therapy and conservative treatment. The tendon's disease is not bad enough to require a



rotator cuff surgical repair but has significant degeneration that will limit function and cause chronic pain.

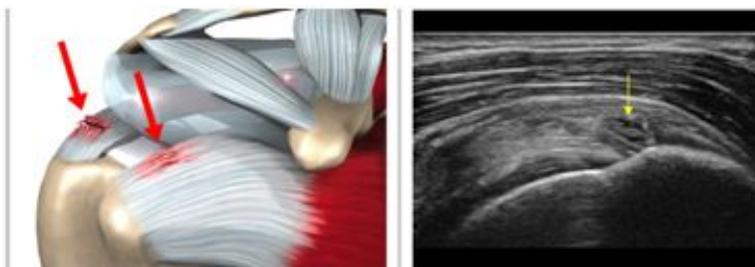
What choices, in the current healthcare system, using traditional sports medicine and orthopedic techniques, are available? There are, in fact, very few treatment options. An interventional, regenerative orthopedic medicine specialist takes a completely different approach with this kind of condition.

Evaluation of the chronic pain, musculoskeletal, orthopedic patient takes time spent with the patient, something that is becoming increasingly less common in visits with physicians. It requires a detailed history and physical assessment, often incorporating a biomechanical assessment. A detailed understanding of diagnostic imaging is also required, and we frequently integrate our own interpretation of MRIs and diagnostic imaging. Relying on the findings of a radiologist who has written a report is often insufficient. Invariably, a detailed ultrasonography examination will also be carried out, directed to all of the muscles, tendons, and soft tissues that can be evaluated dynamically with ultrasound. It takes years of training and experience to master ultrasound technology, to be able to do the proper examination sequence and interpret the findings.



If you have a simple bursitis, then a simple ultrasound-guided injection and some specific exercises might suffice to correct the muscle imbalance that lead to the problem. If, on the other hand, there are more extensive degenerative changes to the tendons of the rotator cuff, or chronic instability of the joint, evaluation and management may be more complex. If degeneration of the tendon progresses far enough, there is no amount of exercise, rehabilitation, laser, acupuncture, or other alternatives that will be able to turn the condition around.

IROM physicians may choose to utilize cellular therapies, such as the use of platelets or stem cells. We have learned through experience, however, that the use of stem cells and platelets may not provide the whole answer in expediting healing of tendons and soft tissue. It also requires detailed understanding of the use of scaffolding and extracellular matrix proteins, growth factors, and other orthobiologic substances that can be incorporated with cellular techniques to alter stem cell differentiation and proliferation to heal orthopedic disease and degeneration.



For example, in the case of the partial thickness tear of the rotator cuff (noted to the left) it may require a precision placement of the needle into the defect under ultrasound. It may also require an injection of extracellular matrix collagen scaffolding. This will be followed by activation of a clotting mechanism that

clots plasma proteins, holding in the stem cells and other regenerative cells that have been injected into the tear.

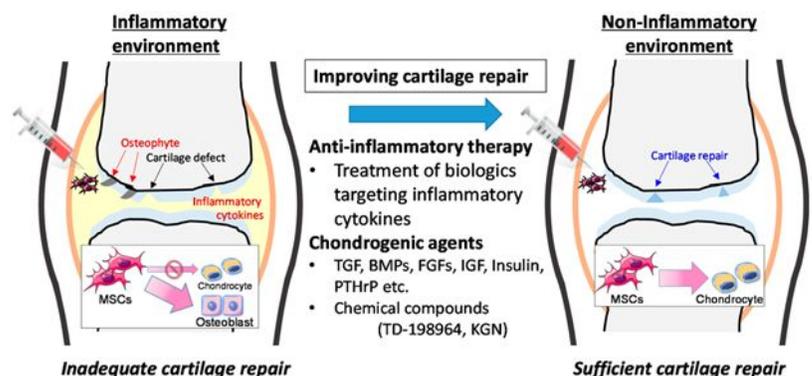
This may be a much more effective method of healing the rotator cuff tear. Although the use of PRP (platelet-rich plasma) injections has become well-known to many physicians, many cases of degenerative tendinopathy may not respond. A practitioner will need to know when to use PRP and when not to. Platelet-rich plasma involves acquiring the patient's blood, separating plasma and platelets, and concentrating the platelets for the purpose of injection. This may improve healing of some soft tissue conditions. Often, though, the use of platelet-rich plasma injections may not be sufficient to resolve a soft tissue injury without combining it with other regenerative techniques.

Precision deployment of these specialized regenerative medicine techniques can result in rapid soft tissue and tendon healing that could not be otherwise possible. Early intervention utilizing these techniques can also provide a means for the injured baby boomer to prevent progressive degenerative changes in the tendon that would lead to full-thickness rupture and surgery.



As a second example, let us consider an individual suffering from knee pain due to a previous injury. Commonly, these individuals will develop progressive pain and disability associated with osteoarthritis of the knee. They will have, more than likely, participated in countless sessions of physical therapy, exercise programs, bracing, nutritional supplementation, injection of steroids, and viscoelastic supplement injections to no avail. Often they will have already had arthroscopic surgical debridement of the meniscus and now face a total knee replacement surgery as the only future option for treatment. Our approach to this patient involves a detailed evaluation, including an evaluation of the biomechanics of the foot, ankle, and gait. This often sorts out the reason the condition has developed in the first place. Specialized gait and biomechanical analysis combined with correction through the creation and use of orthotics is often the first line of treatment.

Ultrasonography examination of the tendons and ligaments of the knee are also critical in examinations of the meniscus. A detailed understanding and interpretation of diagnostic imaging is necessary when working with these patients. It is important to evaluate the specific locations of cartilage defects, including looking for meniscus, ligamentous, tendon, and soft tissue injury. These various soft tissues will often need to be targeted with image-guided procedures. Thus, a detailed understanding of where the problem lies is important.



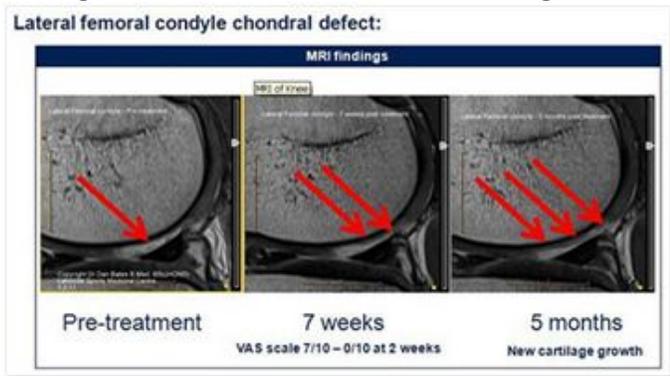
Again, misinformed physicians utilizing stem cell therapies may think that they can treat all arthritic disease with a simple stem cell injection into the joint. This is absolutely incorrect. Patients can have a

stem cells injected directed into an arthritic joint and have little improvement and no significant change on subsequent diagnostic imaging. There are numerous factors that need to be taken into account when making these decisions. Stem cell therapy is only one of the many regenerative medicine tools that may need to be employed in treatment.

For instance, there are only a handful of physicians currently utilizing alpha-2-macroglobulin, a glycoprotein that can be isolated from a patient's blood. This glycoprotein, when injected into an arthritic joint, can inhibit the protein enzymes destroying articular cartilage as part of the inflammatory cascade of osteoarthritis. Even without advanced stem cell therapy intervention, this unique form of treatment can hold off the progression of articular cartilage loss in degenerative joint disease/osteoarthritis.



When stem cell therapies are utilized, we typically combine the stem cells with growth factors and extracellular matrix proteins directed at the ligaments and meniscus attachments. Periodically, intra-meniscus injections may also be carried out in conjunction with injection of protein scaffolding. The ligaments of the knee are common targets for regenerative intervention for the purpose of increasing collagen in connective tissue within the matrix of the ligament and improve joint stability. We are currently working on new protocols in four of our research centers, and will be evaluating a new technique to treat advanced cartilage damage in more severe osteoarthritis patients. This requires injections behind the articular cartilage within the bone marrow. The outcome data in regards to this technique will become available in late 2015 and early 2016.



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## BACK PAIN AND NECK PAIN IN THE BABY BOOMER POPULATION

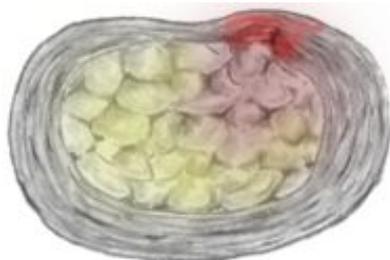
The escalating cost of chronic back pain in the baby boomer population is staggering. From 2006-2007, the cost to treat baby boomers with back pain soared 129%, from \$15.6 billion in 2000-2001 to \$35.7 billion in 2006-2007.<sup>2</sup> The reason for this rise was estimated to be, quite simply, the aging spine.<sup>2</sup> Despite the complexity of spine pain and disorders, the majority of individuals with chronic back pain have an identifiable source of their pain.

Degenerative changes of the facet and sacroiliac joints (marked in red and blue in the picture to the right) are two common sources of chronic back pain. When patients have failed conservative measures they often seek the care of pain physicians as a last resort. Pain medicine physicians' standard method of treatment is to perform a series of corticosteroid injections. This typically provides only short-term



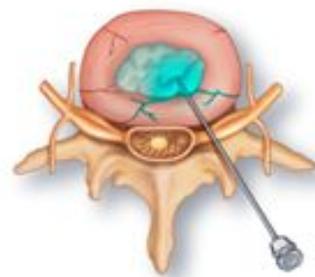
symptomatic relief. It is commonplace for patients to eventually have an ablation of the nerves, innervating the ligaments of the joint with thermal energy (radiofrequency neural ablation). This provides symptomatic relief for about six months, after which the symptoms return. Patients then find themselves caught in a vicious cycle of having to return to the pain physician for interventional procedures until, eventually, this procedure stops working altogether.

On the other hand, an interventional, regenerative orthopedic medicine specialist will perform specific regenerative injection therapies directed to cause a proliferation of collagen and connective tissue within the matrix tissues of the ligaments that support the spine. This stabilizes the arthritic joint and can improve pain and function. It has been our experience that patients have a much better long term outcome with these procedures. Treatment of chronic sacroiliac joint pain is similar. The use of cortisone injections followed by nerve ablation procedures provide transient relief, whereas regenerative procedures to restore the stability of the ligaments can provide better long term outcomes.



Another common cause of back pain in this population is pain from degenerative changes within the disc. There are many stages and manifestations of degenerative disc disease. However, there is very little that conventional medicine has to offer patients with disc pain except for surgical fusion or artificial disc replacement, which involves an extensive surgical procedure.

There are countless minimally-invasive, percutaneous techniques that have been developed over the years, most of which have fallen out of favor. Our research and development centers have been working on an innovative approach for repairing discs, utilizing a fibrin sealant and protein scaffolding in order to seal tears in the disc. This is used in combination with intradiscal stem cell injection. We will be collecting outcome data utilizing this technique over the course of the next two years, but our preliminary results have been positive.



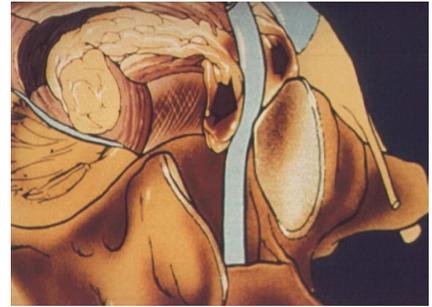
Resolving discogenic back pain and stabilizing segmental instability in this manner can often save an individual from a spinal fusion. Patients with disc pain require a very comprehensive workup, with special diagnostic testing that provides a means of categorizing the internal disc disruption and the type of discogenic back pain syndrome. This provides a way to plan the type of procedure that will be utilized.



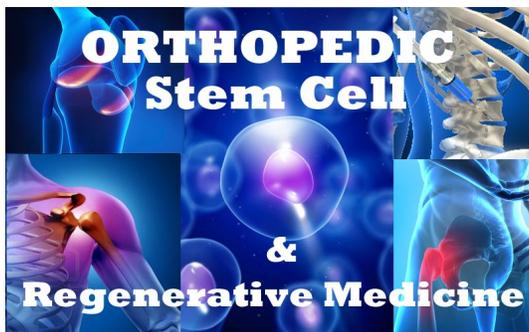
It is common for an older individual with chronic back pain to have multiple pain generators. This often overwhelms physicians trying to sort out the source of the pain. We *always* presume there are multiple pain generators and take painstaking care in utilizing sequential, advanced diagnostic blocks. These determine the sources of pain and typically can be performed in a same-day procedure. They can be done under fluoroscopy (shown to the left), under ultrasound guidance, or both. Once the

pain generators are carefully mapped out, regenerative injection procedures of various types can be utilized to help heal tissues and restore function and stability.

Interventional orthopedic medicine physicians are typically board certified in pain medicine, which requires advanced fellowship training in the use of fluoroscopy-guided and advanced interventional spine procedures. As we have discussed, pain management and interventional regenerative orthopedic medicine physicians are both trained to do advanced procedures. The difference is the methods used to target disease and the utilization of interventions that are focused on regeneration and proliferation of connective tissues to improve chronic pain and function.



As mentioned before, patients with advancing degenerative disc disease and joint disease of the spine require a very detailed evaluation. This evaluation typically takes longer than a 10-15 minute office visit. Providers need to be willing to spend the time necessary sorting out the complexity of these clinical problems. It is not uncommon in our institute for us to spend up to two hours on an initial consultation. Herniated discs (as seen in the picture to the top right) can also be treated conservatively, utilizing various regenerative and minimally-invasive strategies. Again, there are multiple types of degenerative disc disease that can accompany a herniated disc, and these can present clinically in a multitude of ways, creating countless possible combinations. Thus, all of these pain generators need to be sorted out in patients with herniated discs to make appropriate decisions about management.



#### **THE NEW DEMAND FOR INTERVENTIONAL ORTHOPEDIC & REGENERATIVE ORTHOPEDIC MEDICINE**

Hip and knee pain associated with osteoarthritis is a common source of chronic pain in our baby boomer population.<sup>3</sup> Prevalence of hip osteoarthritis ranges from 0.4% to 27%.<sup>4-6</sup> Osteoarthritis (OA) of the knee is even more common.<sup>7</sup> Advancements in medical science and technology are

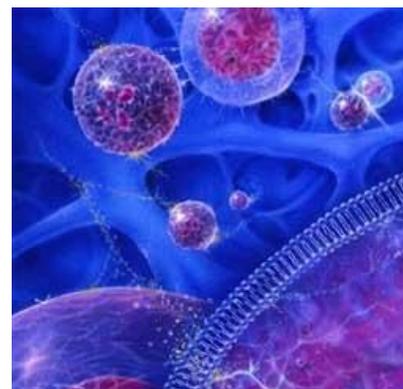
allowing us to live longer. With growing life expectancy, it is expected that we are going to see a higher incidence of musculoskeletal complaints and arthritis of large joints. At present, this is occurring in the baby boomer generation. There has never been a time in the history of medicine when we have had more advanced technology, including methods utilizing regenerative medicine principles, for dealing with the manifestation of aging joints and degenerative joint disease.

According to the Agency for Healthcare Research and Quality, more than 600,000 knee replacements and 285,000 total hip replacements are performed in the US every year. The demand for repeat joint replacement, or revision of the previous joint replacement, will double in the next ten years. As the demand for joint replacement surgery increases, the supply of orthopedic surgeons performing these procedures is declining, which may lead to a demand crisis.<sup>8</sup> Individuals in the baby boomer generation

may have enjoyed great success and lived healthy lifestyles, with few medical problems that would slow them down, and nonetheless find themselves debilitated by orthopedic problems such as hip osteoarthritis. They want to enjoy their success and walk on the beach, play golf, play tennis, and enjoy the fruits of their labor only to find themselves disabled and with chronic pain from osteoarthritis and degenerative joint disease. More often than not it is not just a single joint causing disability but a myriad of orthopedic problems, including back pain, neck pain, knee osteoarthritis, etc. Over just the last few years we have entered a new area of regenerative orthopedic medicine in which alternatives to surgical procedures are more available than in any other time in history. This has created a demand for a “new breed” of physician with specialized training in this field.

## **BREAKTHROUGHS IN REGENERATIVE MEDICINE TECHNOLOGY AT OUR CENTERS**

For years we have been working with bone marrow and adipose tissue-derived (fat-derived) stem cell therapies. One of our frustrations with this technology is the limited number of actual multi-potent stem cells available in these tissues. We worked for several years perfecting stem cell isolation techniques to improve yield. Meanwhile, numerous innovative stem cell biologists and researchers continued to work with various other stem cell technologies. In 2014, we began working with one of the most preeminent stem cell biologists of the last two decades. He had been working on isolation of adult pluripotent stem cells from blood. In collaboration with him, we developed isolation and therapeutic application techniques, utilizing the new technology we have available today. We no longer have to do surgical procedures, such as liposuction, to obtain fat for stem cell procedures nor do we have to do bone marrow taps to do the same. Now, we can obtain higher-quality stem cells with superior cell numbers from blood, using a simple IV blood draw.



This technique has provided us a means to obtain higher numbers of stem cells, with a more homogeneous cell population, and with a much greater potency than we have ever been able to isolate from bone marrow or fat. It has taken us about a year of research and clinical application of this technology to develop comprehensive treatment protocols utilizing this technique. We believe it represents one of the most important discoveries in stem cell technology for future development. We are utilizing these techniques at present in several of our centers across the US and will be conducting extensive clinical trials and research utilizing this technology over the course of the next two to three years.

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