

REGENERATIVE MEDICINE

A Patient Guide

An Unbiased Breakdown of All
Regenerative Medicine Therapies

REGENERATIVE M E D I C I N E

... Sounds impressive but confusing, right? Well in layman's terms it means our bodies were designed to heal themselves! Makes sense... you cut yourself, it heals.

Imagine if pain medication was no longer needed. Imagine if the need for a surgical procedure was prolonged or no longer necessary. Through new technologies in regenerative medicine, there are now treatments available that may enhance your own body's natural ability to heal.

Regenerative medicine is used for the management of pain, sports injuries, to expedite the healing from surgery, hair loss and even to combat the signs of aging.

We know that choosing what type of regenerative medicine therapy that works for you may be confusing. For that reason, we have created this unbiased booklet to help you make that decision.

Our goal is to provide you with the information needed when discussing Regenerative Medicine options with your physician.

It is important to make an educated investment in your health care. Live your life the way it was meant to be lived.



REGENERATIVE M E D I C I N E

From the young model to the aging retiree, from the elite athlete to the weekend warrior, to the immune- compromised patient and the patient with other co- morbidities, clinicians continue to search for ways to control pain and accelerate the healing process. Utilizing various therapies has proven to have many profound benefits; not the least of which includes overall superior outcomes.

Dawning on the horizon of medical advancements, these therapies hold the potent healing potential whose benefits have the power to span disciplines as diverse as hair restoration and orthopedics. These therapies harness the power and versatility of the human body to regenerate damaged skin, accelerate healing, reactivate hair follicles, heal wounds and alleviate pain.

Many people have heard of the usefulness of stem cell therapy but there's so much more to regenerative medicine than just stem cells, whose outcome is very dependent on the age of the patient they are being harvested from; your stem cells are as old as you are. (Figure 1) Equally important are components such as collagens, cytokines, proteins, growth factors... the list goes on.

Treatments being utilized, as a stand-alone or combined, include birth tissues from amniotic fluid/membrane, umbilical cord tissue, umbilical cord Wharton's Jelly and umbilical cord blood, platelet rich plasma (PRP), adipose derived stem cells (ADSC) and bone marrow aspirate (BMA). (Figure 2)

Impact of aging on the ratio of MSCs to bone marrow cells
(A. Caplan 1994)

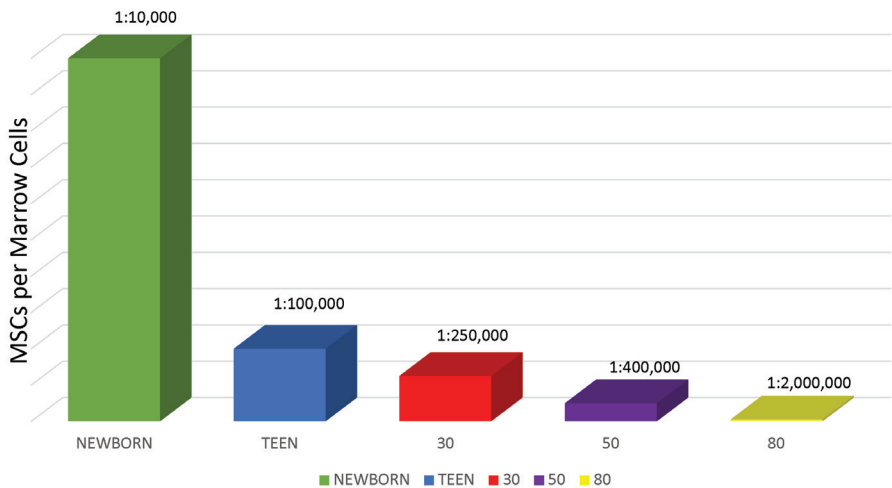


FIGURE 1

	Amnion Fluid	Platelet Rich Plasma (PRP)	Umbilical Cord Tissue	Adipose Derived Stem Cells	Bone Marrow Derived Stem Cells	Steroid	Hyaluronic Acid
Source	Amniotic Tissue	Platelets	Birth Tissue	Adipose Tissue	Bone Marrow Aspirate	Synthetic	Synthetic
Anti-Inflammatory	●	●	●	●	●	●	
Anti-Microbial	●	●	●	●	●		
Growth Factors	●	●	●	●	●		
Non-Toxic	●	●	●	●	●		●
Pluripotent	●		●	●	●		
Mesenchymal Stem Cells			●	●	●		

FIGURE 2

WHAT IS REGENERATIVE MEDICINE?

Regenerative medicine is a form of tissue engineering and molecular biology which deals with the "process of replacing, engineering or regenerating human cells, tissues or organs to restore or establish normal function". When injured or invaded by disease, our bodies have the innate response to heal and defend. Harnessing and enhancing the body's own regenerative powers is a medical practice at the frontier of present-day advancements whose properties may seem miraculous to those who benefit from them. The miracle, however, is the result of scientific exploration that has begun to unlock and utilize the body's extraordinary ability to heal and restore itself.

Many patients have turned to regenerative medicine for a treatment option that may help them recover from sports injuries, alleviate chronic pain and even combat the natural effects of aging and the impact on their aesthetic appearance. While regenerative medicine therapy is often associated with stem cells, there are many regenerative components that can be used to create effective treatments that enhance the body's natural ability to heal. These therapies have helped countless patients manage their pain, recover from injuries sooner and rejuvenate their appearance.

HOW DOES REGENERATIVE MEDICINE WORK?

Cells are the building blocks of tissue, and tissues are the basic unit of function in the body. Generally, groups of cells make and secrete their own support structures, called the extracellular matrix. This matrix, or scaffold, does more than just support the cells; it also acts as a relay station for various signaling molecules. Thus, cells receive messages from many sources that become available from the local environment.

Each signal can start a chain of responses that determine what happens to the cell. Through medical technology we can now understand how individual cells respond to signals, interact with their environment and organize themselves into a healing process. Scaffolds are created utilizing various regenerative medicine therapies allowing for the issue " self-assemble".



WHAT CAN REGENERATIVE MEDICINE BE USED FOR?

PAIN MANAGEMENT

Pain for most of us comes and goes; some stays and you live with it day in and day out. Imagine a life where pain is constant, taking control of your life and, in some ways, the life of those close to you. Imagine having to rely on a narcotic to somewhat lessen the pain just to make it through the day. The Institute of Medicine of The National Academies state that over 116 million Americans suffer from chronic pain, 1.5 billion worldwide. Pain that is caused by trauma, aging, sports injuries, work-related injuries, diseases, the list goes on and on.

Drugs are the "first line" of treatment for most forms of pain. To date, the goal of successful pain management is to effectively control patient pain without causing side effects from the medication prescribed. However, only 58% of those who took prescription pain medicine received any form of pain relief and only 41% of those taking over-the-counter pain medication reported relief. The incident of unintentional (and preventable) drug overdose-related deaths is growing exponentially. Of all drug-related deaths in the U.S., 43% are due to pain relief medication.

PAIN MEASUREMENT SCALE

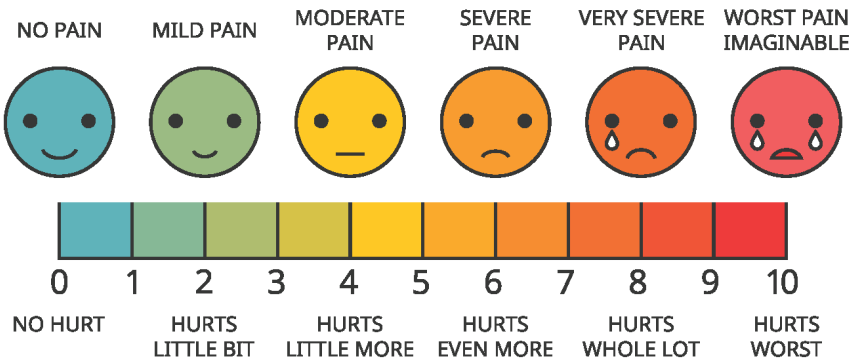


FIGURE 3

Doctors know that approximately 50% of all patients undergoing pain management will not receive adequate relief (Figure 3) at first dosing and/or are at a higher risk of experiencing adverse, potentially life- threatening events.

80% of all pain management drugs are prescribed by the general practitioner or the internist. With the epidemic of opioid abuse so prevalent, clinicians are looking for other methods to treat pain and injuries through injection therapy and patients, in turn, are looking for non-invasive options to avoid any type of surgical procedure. With the advancement of medical technology, regenerative medicine is now a popular and successful alternative to treat the management of pain.

SPORTS INJURIES

Sports for professional and recreational purposes are mainstays in American society, but unfortunately so are sports-related injuries. As recent studies increasingly prove the inefficiency and harm of commonly-used treatments like anti-inflammatory medications and corticosteroid injections, more injured athletes are seeking regenerative medicine therapies to heal.

Regenerative medicine is now at the forefront of offering such treatments to help athletes overcome injuries without surgery or invasive measures.

Sports injuries are most often musculoskeletal conditions that occur in the hip, knee, elbow, ankle, shoulder and foot. (Figure 4) Since tendons, ligaments, cartilage, and bones in that area of the body don't receive a great deal of blood flow, the body can't always heal and regenerate itself effectively. Regenerative medicine therapies offer a new and efficient treatment option that can augment the body's natural healing process and rebuild damaged tissue.



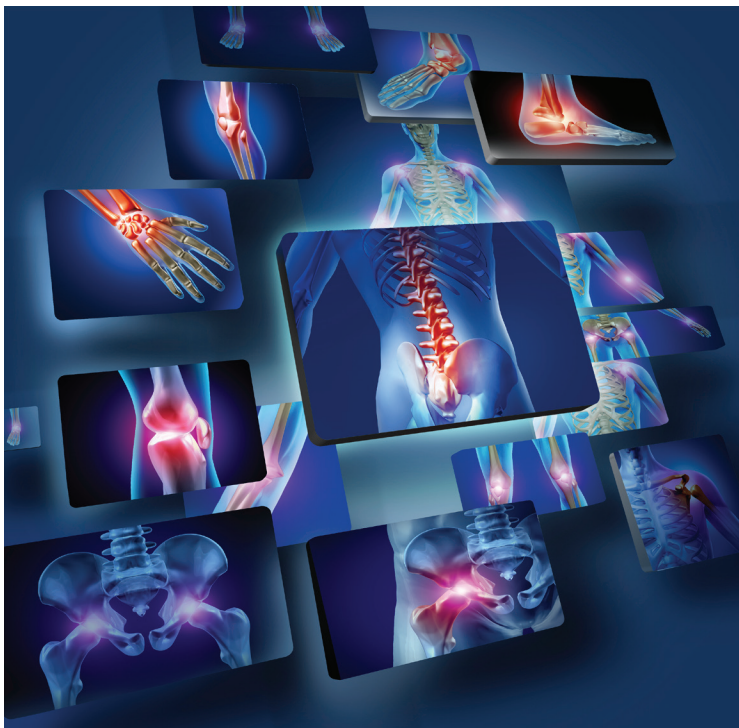


FIGURE 4

When treating articular cartilage injuries, for example, regenerative medicine therapies can both overcome the limited ability of the cartilage to self-repair by providing either new cells or growth factors needed to repair the existing cells. Studies indicate that such techniques can improve the efficacy and consistency of treatment and reduce the potential for future injuries in the same location. Professional and recreational athletes now have a safe and efficient alternative to surgery that not only resolves pain but also thoroughly heals difficult injuries.


ANTI-AGING

In addition to baby boomers, now being an average age of sixty-three, the younger generation is feeling the pressures of today's society which has placed a tremendous focus on personal appearance. As recent as ten years ago, the average age for a woman having some type of anti-aging procedure was forty-seven; today that average age is thirty-five. Patients, both men and women, are having cosmetic treatments prior to the aging process becoming apparent in their appearance.

Regenerative medicine is gaining popularity in the fight against aging. Anti-aging procedures are becoming the fastest growing treatments in cosmetics. Treatments being utilized include platelet rich plasma, also known as the Vampire Face Lift, bone marrow aspirate, amnion liquid and umbilical cord tissues and blood, all being marketed as "stem cell therapy." (Figure 5)



FIGURE 5



"Approaching the age of 60 I noticed the signs of aging were catching up to me, especially in the lip area. Over the past decade, I have had Botox and facial fillers, but none seemed to last more than a couple of months and I tended to bruise and swell substantially. During a consult with my plastic surgeon, he suggested I try regenerative medicine, along with a facial filler comprised of hyaluronic acid. To my surprise, I experienced no swelling or bruising post-treatment. I am delighted with the results and, after several months, I see no signs of the effects diminishing."

Vicki, C.E.O, Age 61

HAIR RESTORATION

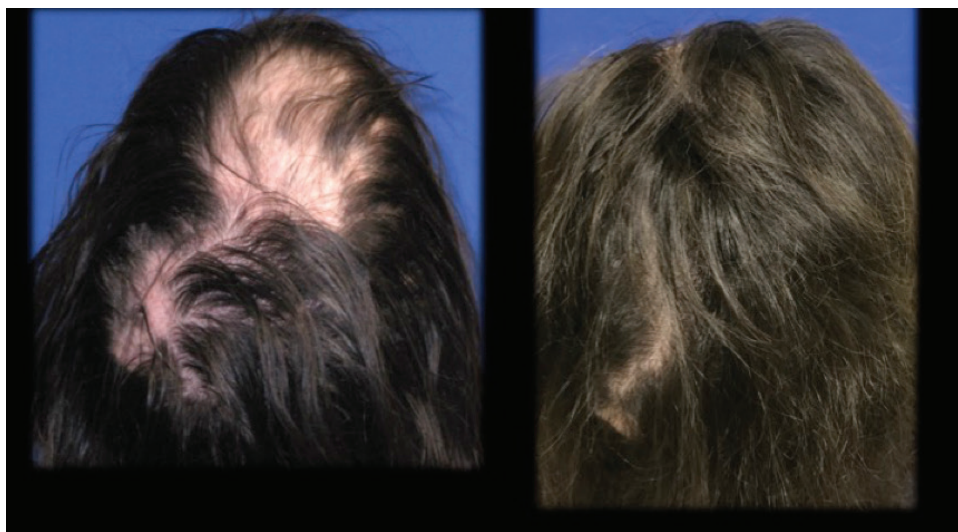
According to the American Hair Loss Association, two-thirds of men will experience hair loss by the age of 35. But women are also affected, making up 40% of all hair loss sufferers. Hair loss around the face affects 90% of all males and females during the aging process and is one of the strongest contributing factors to low self-esteem. In addition, the psychological damage caused by hair loss and feeling unattractive can be just as devastating as any serious disease, and in fact, can take an emotional toll that directly affects physical health.

The most common cause of hair loss is a hereditary condition called male-pattern baldness or Female-pattern baldness. It usually occurs gradually and in predictable patterns- a receding hairline and bald spots in men and thinning hair in women. Alopecia Areata is also a major cause of hair loss.

During the last ten years or so, there has been great promise for being able to treat hair loss by using regenerative medicine therapies. Regenerative medicine may work in numerous ways to improve and regenerate hair by providing nutrition and promoting new blood supply to the follicle; increasing hair shaft size. Additionally, studies show growth factors reduce inflammation in the scalp and turn on follicular stem cells.



*PATIENT TREATED WITH
UMBILICAL CORD TISSUE AND PRP*



*PATIENT TREATED WITH
WHARTON'S JELLY AND PRP*

WHAT THERAPIES ARE AVAILABLE?

BIRTH TISSUES

Birth tissue is donated by healthy mothers at the time of a scheduled cesarean section. Through an informed consent process, expectant mothers submit their past medical and social history which is prescreened through an extensive and complete medical review and pre-natal evaluation. This process is performed prior to delivery utilizing the protocols established by various regulatory agencies. Additionally, prior to delivery, the mother is tested for communicable diseases following the requirements of the Food and Drug Administration (FDA), Center for Disease Control (CDC), and the American Association of Tissue Banks (AATB). The recovery is performed by specifically trained technicians at the time of the delivery.

Birth tissue has been used for over 100 years for a broad range of therapeutic applications. However, it is only recently that birth tissue was discovered to have great clinical benefit when cryopreserved to protect its residual cells. Since the discovery of birth tissue as a viable cellular matrix in 2005, there have been no reports of adverse events or disease transmission. Additionally, birth tissue is considered immune privileged and as such does not express Class II antigens (your body cannot reject).

Finally, Birth Tissue products are easy to use as it can be applied directly to the injured site. To date, tens of thousands of patients have been treated with these types of products.

Some people may hesitate at the idea of birth tissue. Be assured that the tissue is obtained from healthy, carefully screened mothers at the time of a scheduled cesarean section and causes no harm to her or her newborn.



AMNIOTIC FLUID THERAPY

Patients considering invasive stem cell injection treatment to aid in pain management, recovery, or healing may want to consider the rejuvenating qualities provided by amniotic fluid. This all-natural regenerative therapy is a liquid amnion allograft composed of amniotic fluid and features many components that enhance the body's natural healing process. (Figure 6)

Just as the amnion (innermost layer of the placenta) protects the fetus during development, it can also provide the same protection to injured or traumatized tissue. Amnion contains collagen substrates, the full range of growth factors, amino acids, carbohydrates, cytokines, hyaluronic acid, fibroblasts, epithelial cells and extracellular matrix. Amniotic fluid has proven to be multipotent and capable of differentiating into adipogenic, osteogenic, myogenic, endothelial, neurogenic and hepatic cell lineages.

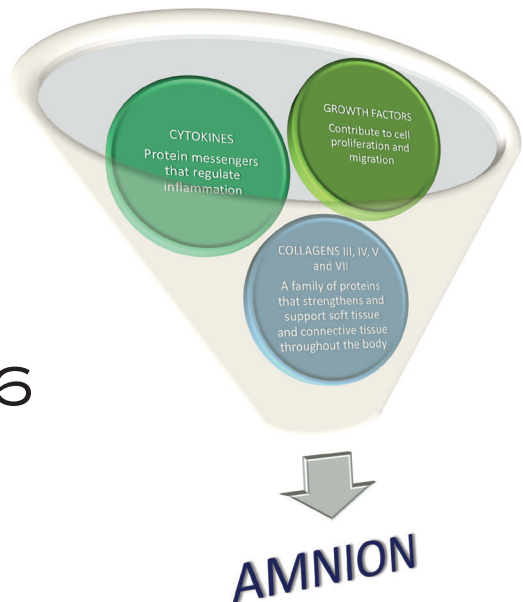


FIGURE 6

Amnion membrane is rich with the basic components necessary for tissue regeneration providing an antimicrobial environment. It also contains anti-inflammatory characteristics with anti-adhesion/anti-fibrotic capabilities. To remove the risk of graft-host reaction, the chorion, which has been shown to contain maternal antigens, is removed. This will maximize the potential benefits of amniotic membrane in a variety of medical specialties. Additionally, the immunologically privileged nature of amnion membrane has been shown in a multitude of research papers.



UMBILICAL CORD TISSUE

Also derived from birth tissue within the umbilical cord is the Wharton's Jelly. Wharton's Jelly, is the tissue surrounding the umbilical vein and vessels in the cord. (Figure 7)

When the vessels are removed closer to the fetal side of the cord, you have remaining tissue which contains stem cells termed mesenchymal stem cells or MSCs. MSCs are undifferentiated cells (not changed) that have the capacity to change into any specific cell type in the body. These cells, once deployed to any area of injury or disease, can readily change into the cell type that is needed to repair. Moreover, MSCs are directed to the body's cell signals that recruit them to the site of the injury. Once they reach this area, they dock and begin repairing by releasing cytokines, growth factors and other components that are needed in the healing process.

Derived from the maternal side of the umbilical cord, this tissue containing up to 50 times more growth factors and other components than the amniotic fluid. Wharton's Jelly products are especially beneficial for patients over forty that, due to the aging process, have less viable cells than a younger patient would have. (Figure 8)

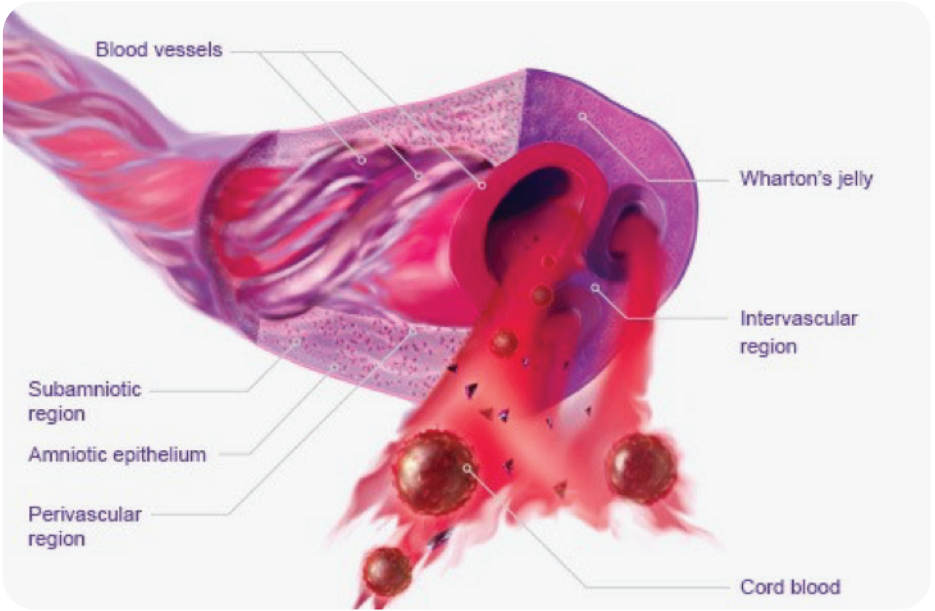


FIGURE 7

Impact of aging on the ratio of MSCs to bone marrow cells
(A. Caplan 1994)

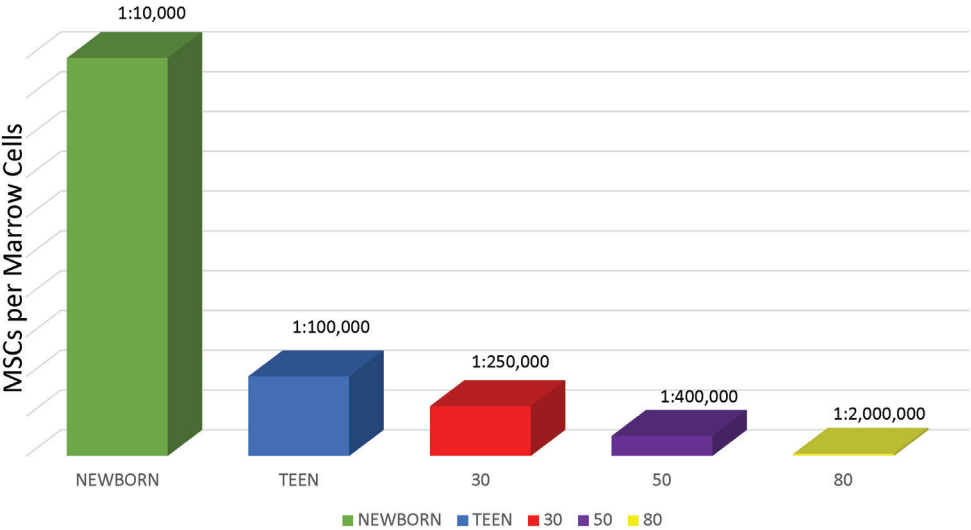


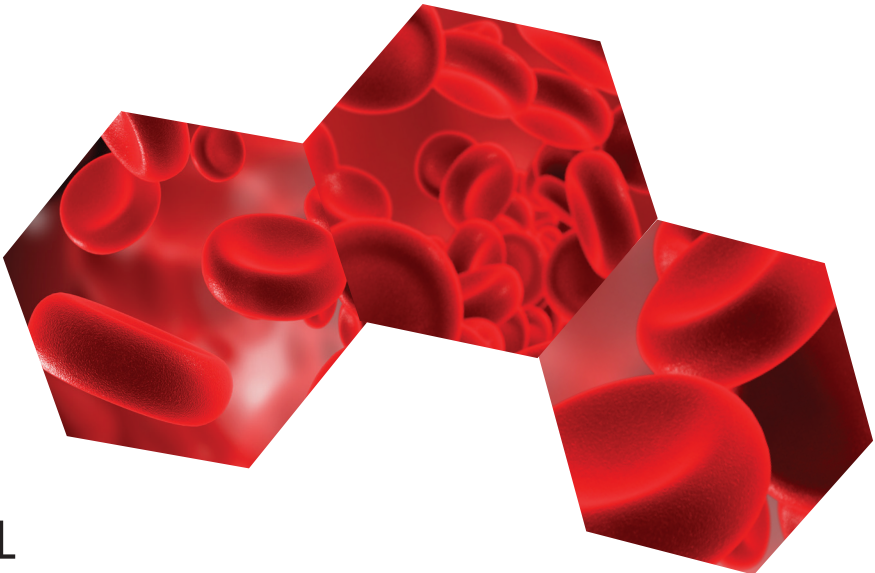
FIGURE 8

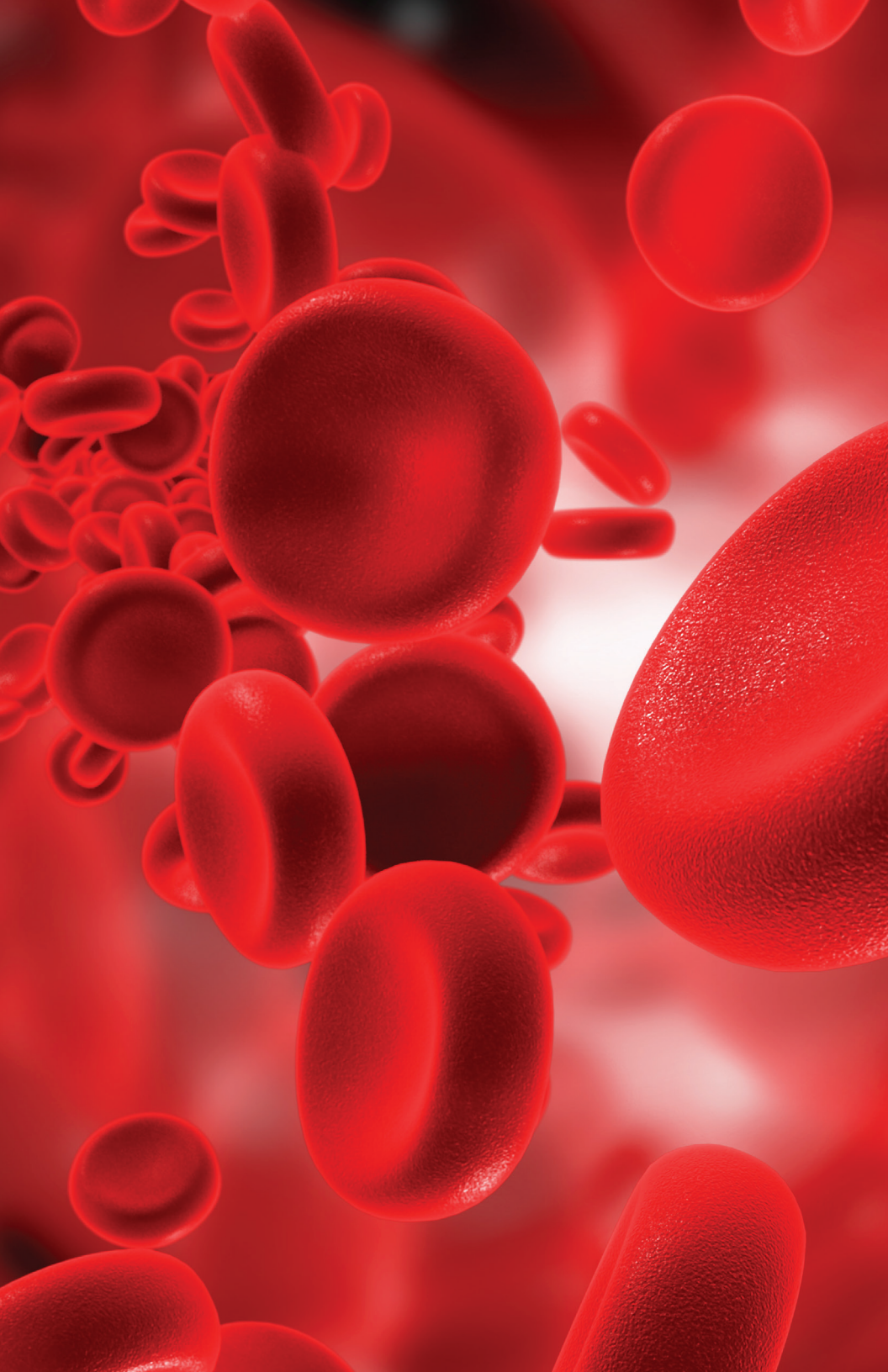
UMBILICAL CORD BLOOD

Umbilical cord blood is blood that remains in the placenta and in the attached umbilical cord after childbirth. Umbilical cord blood contains stem cells, which can be used to treat hematopoietic and genetic disorders.

These stem cells have the capacity to self-renewal, release growth factors and cytokines, as well as differentiate into more mature cells.


As an extension of fetal cells, umbilical cord blood cells exhibit high plasticity. Umbilical cord stem cells have been used for over twenty years for hematopoietic stem cell reconstitution as a substitution for bone marrow reconstitution. Additionally, due to the high plasticity of umbilical cord cells, there is significantly decreased risk of graft-versus-host disease (GVHD) and if GVHD does occur it is less severe than most other types of transplants.







"As a long sufferer from degenerative knee pain, I have tried multiple products to maintain my healthy, active lifestyle. My goal every year is to enjoy a skiing season without having to take days off for knee pain and swelling. As a physician, I keep up with medical developments and was excited to hear about the latest regenerative efforts from regenerative medicine therapy. The science is solid and credible and supports what I have discovered in my own wound healing research. I had an injection of umbilical cord tissue into each knee 4 months before the first ski trip of this year. I was cautiously optimistic after six weeks when my knees had less daily discomfort and made less 'noise' when I flexed them. I am thrilled to report that I could ski six full days in a row without my usual swelling and pain. I didn't use any anti-inflammatory medications and didn't need to ice my knees one time, even after a day of 30,000 vertical feet. The results exceeded expectation. I am recommending this revolutionary regenerative product to my friends and to my patients."



**Dan, M.D.
Plastic Surgeon,
Age 60**

PLATELET RICH PLASMA (PRP)

Often misrepresented as stem cell therapy, PRP is created by drawing venous blood from a patient with an anticoagulant, injecting it in a special tube and placing the tube in a centrifuge. The high speed of the centrifuge separates the platelets (Figure 9) from the red blood cells. The product is then re-coagulated with thrombin and sometimes mixed with calcium chloride to induce the release of growth factors. The PRP is then ready to be used as an autologous tissue injection or introduced to a surgical site.

Platelets are normally known for their responsibility to clot blood, but they also contain proteins known as growth factors that play a vital role in healing injuries. Since the location of most sports injuries does not receive an abundant flow of blood, the injuries are deprived of the platelets and growth factors needed to regenerate damaged tissue. Studies show that PRP treatment can resolve that problem by delivering the injured part of the body with the platelets necessary to support healing.

While not as "potent" as other therapies, PRP does contain growth factors and other cytokines that are said to recruit cells to an area of injury to coordinate a repair response. Additionally, PRP activates tenocytes to proliferate quickly and produce collagen to repair tissue.

PRP is said to begin working in a few weeks but, alone, can take 6-9 months to its full effect. However, PRP mixed with New Life Regenerative Medicine products may enhance the healing process and cut the time down by more than eighty percent.

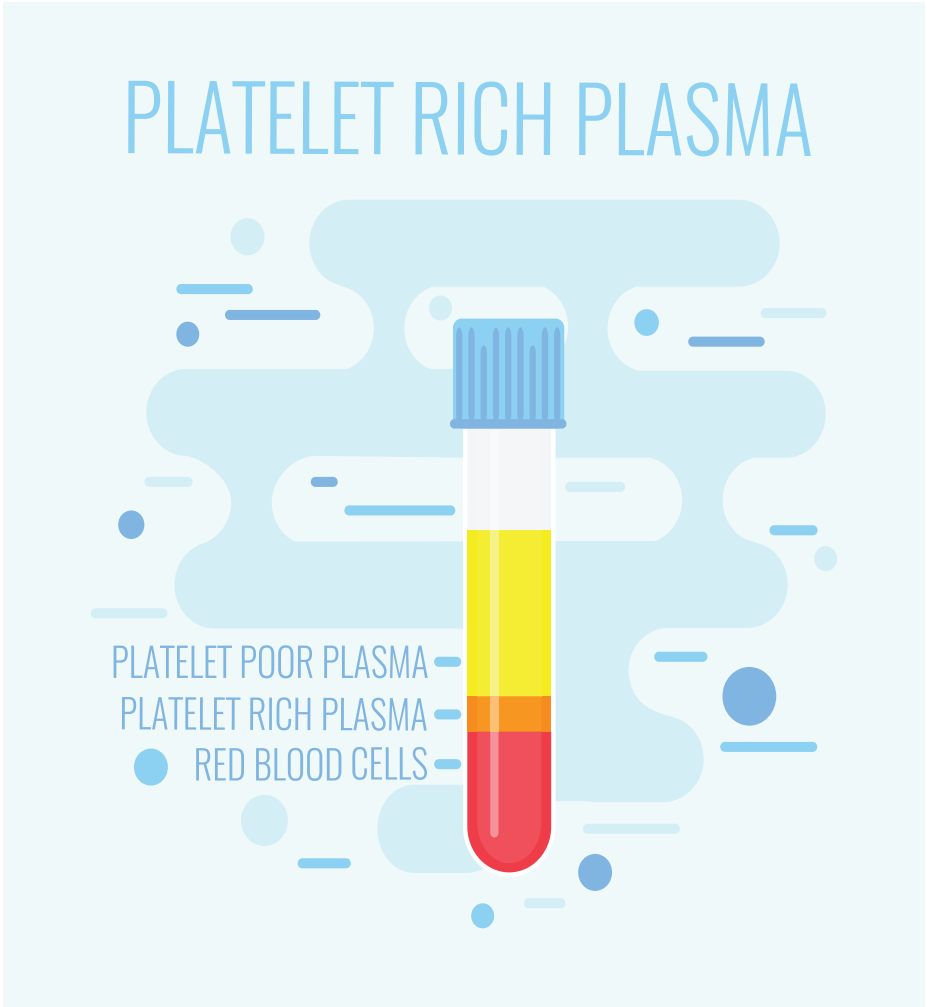


FIGURE 9

ADIPOSE DERIVED STEM CELLS

Adipose (fat) is collected from the patient via mini-liposuction. This procedure should be performed by a licensed physician in a hospital setting under light general anesthesia. The physician will determine the most appropriate location(s) to perform the incision(s) for the required fat tissue extraction. One of the most frequently used areas is the commonly referred to "love handles." The procedure typically takes about an hour. After the procedure, patients are observed for one hour in the post-op recovery room and then an additional one to two hours in another recovery room. Pain medication is prescribed for those who need it although most patients require very little medication

While recovering, your stem cell will be separated from your fat tissue and the doctor will then inject those cells (just like getting a shot or an IV) back into your body. (Figure 10) The entire procedure normally takes four to five hours and the number of viable cells obtained is greatly dependent on the age of the patient.

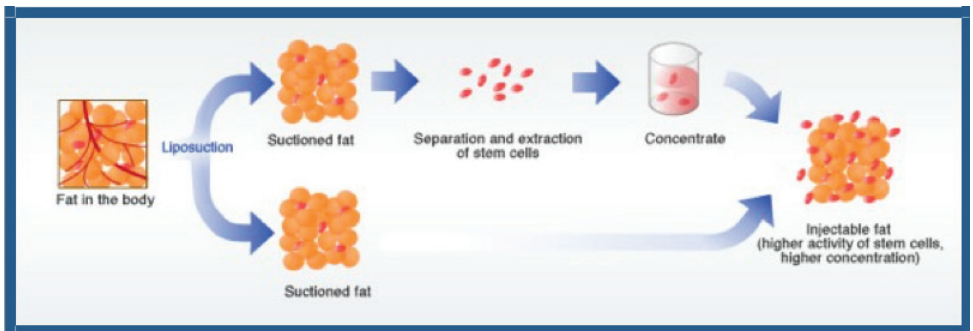


FIGURE 10

BONE MARROW ASPIRATE STEM CELLS

Bone marrow aspirate concentrate is made from fluid taken from bone marrow. A needle is used to remove bone marrow from within the bone. This is typically done under sedation or general anesthesia. Marrow is commonly taken from the pelvis but may be taken from other sites. The pelvis is marked and prepped to keep the site sterile. A hollow needle is inserted into the bone and a syringe is used to withdraw fluid from the bone marrow. (Figure 11) After enough fluid has been collected, the needle is removed. Pressure is applied to the needle site to stop the bleeding. A small dressing is then applied. After aspiration, there usually is pain at the pelvis that goes away within several days. A small dressing or bandage is kept at the aspiration site until it has healed.

The sample of bone marrow is removed and then spun down in a centrifuge to separate the cells. A liquid is produced that has a high concentration of stem cells. The physician injects the stem cells directly into the surgical site. This method is avoided in patients who have an infection or cancer. Complications may include pain, bleeding, infection and nerve injury. An intra-abdominal injury may occur because of the needle. The success of bone marrow aspirate stem cells is dependent on the age of the patient.

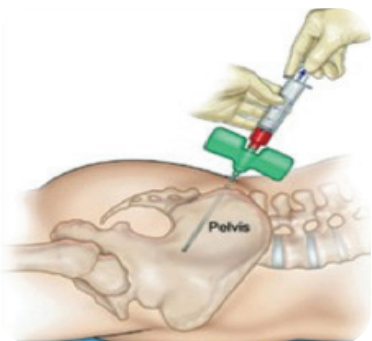


FIGURE 11



TESTIMONIALS

"Playing in the NFL for twenty-one years as a quarterback has taken a toll on my body leaving me with chronic pain in my shoulder. Although retired from the NFL, I continue to lead an active lifestyle by working out and playing golf. When the pain in my shoulder became too much to enjoy these activities, I went to my good friend, Dr. Mic McClimans who suggested I try regenerative medicine therapy, including birth tissue stem cells, provided by New Life Regenerative Medicine. It has now been two months since my treatment and the improvement is substantial; I am sleeping better; my golf game has improved, and the pain has substantially subsided. Overall, I would say that the New Life Regenerative Medicine products administered by Dr. McClimans have improved my quality of life."

Vinny Testaverde
Retired NFL Quarterback
Age 54

"I am pleased to be one of the recipients of Regenerative Medicine through a knee injection. My knee was injured 45 years ago (patella dislocation resulting in traumatic shearing of meniscus cartilage). Prior to injection, I couldn't play golf without a cart. Playing multiple days in a row routinely resulted in minor swelling. I had the injection in late August. At the end of September, I spent a week in the Hamptons and played multiple rounds of golf. More impressively, I could play tennis and some basketball. Although my athletic prowess was far short of noteworthy, my knee was exceptional; I had no swelling. Clearly, this has been a very positive result for me."

Jim
Businessman
Age 73




"After learning that I needed a total knee replacement at 69 years old, it concerned me. My doctor suggested an alternative procedure, regenerative medicine. I was skeptical at first and since he could not guarantee the treatment this concerned me. I trusted his recommendation and the procedure was done in June 2016. I had one injection. As of today, January 2017, I can happily report it was successful. I have no pain, swelling and my range of motion at my age is exceptionally better after this injection. I thank [my doctor] for his recommendation and inform others to consider it before having a total knee replacement."

Melba
Retired
Age 71

"Suffering from shoulder pain for many years, I finally decided to schedule shoulder surgery. Fortunately, prior to having the surgery done, a colleague recommended I try amniotic fluid therapy. The first week after my injection I was skeptical as to the efficacy but by week three I had significant improvement and decided to cancel my surgery. Months later, I still feel great!"

Mick
Orthopedic Surgeon
Age 64



"Truly, the most important investment we can make, with the greatest return, is in the health and duration of our lives, so that we may fully enjoy our family, friends and fruits of our labor."



New Life

Regenerative Medicine®

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