INTEGRATIVE IMAGING
COLLEGE OF INTEGRATIVE MEDICINE

Guidelines for Regenerative Injection Therapy (RIT) utilizing Platelet Rich Plasma (PRP) Orthopedic Medicine Practice

6 C's of MAXIMIZING EFFECTIVENESS OF PRP TREATMENT

1. **Collaborate** with patient's Primary Care b Provider (PCP) and physical therapist or Chiropractor to arrive at the **correct diagnosis**.
2. **Coordinate** previous/existing health care with up-to-date imaging to provide the patient with the dignity of a **proper diagnosis**.
3. **Collate** all prior medical and surgical history.
4. **Correlate** pharmaceutical history.
5. **Communicate** overview of regenerative injection therapy (RIT) in sync with patient's existing health care regimen (PRP therapy is **'in addition to'**, not **'instead of'** the patient's existing and evolving 'patient specific' health care regimen).
6. **Complete** patient registry.

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http://www.swarminteractive.com/patient-education/website-review.html

1. Correlate with primary care providers and physical therapist to arrive at the diagnosis.

- **The patient-centered medical home (PCMH)** is the offspring of the **Affordable Care Act** that, among other things, mandates that, going forward, Primary Care physicians must acquire and store all patient electronic health records (EHR). The mandate was presumably designed to encourage us to provide high-quality care, but achieving a PCMH practice will require an expensive and cumbersome organizational overhaul. The evolution of our College of Integrative Medicine (coimed.org) over the last several years had already been introducing many of these changes into our practices.

- The impetus for doctors to accept major change to their profession is here. Most doctors are dissatisfied with their jobs, and less than half would choose a career in medicine if they were able to do it all over again. There are many reasons for the dissatisfaction. Most doctors enter the field thinking they'll be able to spend most of their time healing the sick. Yet the paperwork burden on doctors has become crushing. Administrative tasks account for nearly one-quarter of a doctor's day, and will become even more complicated under the **Affordable Care Act**.

- **Family Practitioners** are the "descendents" of the original physicians, and Family Medicine will do well in any system or non-system. However, the future for **Specialty trained physicians** is not so clear. Our COIMED group, recognizing the fundamental flaws in the fragmented US health care system, saw the potential of an integrative/generalist approach to medicine by training **Orthopedic Medicine Specialists**.

- Common **musculoskeletal injuries** account for nearly **100 million office visits annually** in primary care and orthopedic clinic settings in the United States. **PRP is seen by many orthopedic, primary care and sports medicine physicians** as a new treatment option for tendon, muscle, and bone injuries.

- Our goal is to organize like minded individuals to help transform the discipline of family medicine. We are introducing the concept of primary care in conjunction with pain medicine and Regenerative Injection Therapy practice. We are showing how safe and relatively inexpensive Cellular Medicine can successfully meet the needs of our patients in this changing health care environment. We no longer place the total focus just on our practitioners, but also on our allied health care providers, office staff and most importantly on our patients.

- Patients will seek out those practitioners who both provide the services they want and those who perform those services well. Our regenerative medicine practitioners are educated and trained by the American Association of Orthopedic Medicine (AAOM). Our biologic regenerative therapy protocols are approved by the Institutional Review Board (IRB) of the International Cellular Medicine Society (ICMS). And our clinics are certified by the ICMS.

- According to the World Health Organization (WHO), **musculoskeletal injuries are the most common cause of severe long-term pain and physical disability**, and affect hundreds of millions of people around the world.

- **2000–2010 has been termed ‘‘the decade of bone and joint’’** as a global initiative to promote further research on prevention, diagnosis, and treatment.

- Soft tissue injuries, including tendon and ligament trauma, represent **45% of all musculoskeletal injuries in the USA.**

- **Platelet Rich Plasma (PRP) grafting techniques** are now being utilized in musculoskeletal medicine with increasing frequency and effectiveness. **Clinical studies have reported that PRP use can shorten recovery time, enhance bone strength, produce bone healing in a shorter time, decrease the wound infection rate, and reduce surgery-related swelling and pain**.

- **PRP - Practical Considerations**
    - Proper diagnosis
    - Pre-injection patient screening lab work
    - Pre-injection manual therapy assessment of the kinetic chain
    - Injection technique
    - Approach
    - Anesthesia
    - Guidance
    - Post-injection care & rehab

- **Soft tissue injuries** treated with PRP include:
    - tendinopathy,
    - tendinosis,
    - plantar fasciitis
    - acute and chronic muscle strain,
    - muscle fibrosis,
    - ligamentous sprains, and
    - joint capsular laxity.

- **PRP** has also been utilized to treat **intra-articular injuries** including:
    - arthritis,
    - arthrofibrosis,
    - articular cartilage defects,
    - meniscal injury, and
    - chronic synovitis or joint inflammation.

- Before the PRP injection, the patient is informed of the procedure and potential risks and benefits similar to other interventional procedures.

- Theoretical risks related to the interventional procedure include:
  - Infection,
  - Hemorrhage
  - Soft-tissue injury

- There have never been a single reported case of severe or adverse reactions as a direct consequence of any cellular medicine procedure- ever.

- Carcinogenesis?
  - Growth factors act on cell surface receptors only, **do not enter the cell**, and **do not cause DNA mutation**.
  - There is **no plausible mechanism** by which growth factors would result in neoplastic development.
  - Growth factors (PGF) activate normal, rather than abnormal, gene expression.

- The use of sterile technique and a probe cover if using ultrasound guidance is warranted. In general, PRP is avoided when there are signs of local inflammation or infection or if there is a history of malignancy.
- The patient is also educated with regard to short-term and long-term expectations. Because the injection of PRP induces local inflammation, pain should be expected after the procedure.

- Nonsteroidal anti-inflammatory drugs are also avoided 2 weeks prior and at least 2 weeks after the procedure so as to not inhibit the effects of growth factors and the healing response.

- Although the follow-up protocol may vary, patient specific physical therapy beginning 10 to 14 days after the procedure is considered an integral component to improve the long term success of the procedure.

Physical Therapy Pre-Procedure (3-C's)

1. **Coordinate** with existing physical therapist, chiropractor, manual therapist or osteopathic physician to arrive at **the proper diagnosis**.
2. **Correlate** clinical and imaging findings with new physical therapy provider (if patient doesn't have existing relationship).
3. **Collaborate** with patient's Primary Care Provider and Physical Therapist with proposed time course to be followed subsequent to regenerative injection therapy. Relationships among members of the primary care team have been shown to be vital to the development of effective practices.
4. **Communicate** with patients asking them about their triad of:
   1. Ideas,
   2. Concerns and

3. Expectations for their health care

Prior to the utilization of these PRP matrix grafting protocols our group recommends appropriate first line therapies such as:

1. Relative rest
2. Appropriate bracing and kinesiotaping,
3. Evaluation of core stabilization
4. Reintegration of kinetic chain mechanics
5. Physical/manual therapy—with or without eccentric loading protocol

- ## Advice to Keep Back Pain from Becoming Chronic

Chronic low back pain causes a lot of misery and accounts for the majority of health care costs associated with back problems. Is there a way to prevent back pain from becoming chronic? A recently published study in *Disability and Rehabilitation* suggests that **cognitive behavioral therapy (CBT) combined with physical therapy may help.**

Investigators reviewed high-quality medical studies of back pain treatment published between 1992 and 2011. The studies included only patients who had low back pain with no identifiable cause for less than 12 weeks.

Their findings suggested that a form of cognitive behavioral therapy called operant conditioning might help prevent chronic back pain. In this therapy, patients with acute low back pain work with physiotherapists to increase their levels of endurance and perform muscle-conditioning exercises gradually, but according to a firm schedule.

They learn that **pain during exercise may hurt, but this does not mean it harms**. They also learn to recognize negative thoughts about the back pain and replace them with more positive attitudes.

Fear avoidance, depression and catastrophizing (viewing a situation as worse than what it is) can increase the suffering caused by acute back pain. Ask your doctor if this type of cognitive behavioral therapy/physiotherapy could help you in your struggle with back pain, especially in preventing the condition from becoming chronic.

- ## Smoking cessation

- **Correct endocrine imbalances;** hypothyroidism, low testosterone, etc. - have the patient's primary care provider measure several key lab values prior to procedure to make sure there are no underlying systemic diseases or comorbidities that could interfere with regenerative injection therapy. Normalize hormone levels (including thyroid- T3 and T4, TSH, testosterone, Estradiol, etc.).

- **Nutrition:** Probiotics, protein (vegetarians have poor outcomes with PRP), vitamin C, zinc, magnesium, vitamin D, Coenzyme Q, balanced omega 3 and 6.

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The Anti-Inflammatory Diet, Part 2: Foods That Affect the Inflammation Response

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By G. Douglas Andersen, DC, DACBSP, CCN

As promised in part 1 of this article (Sept. 23 issue), this installment includes lists of foods that tend to up-regulate and down-regulate the degree of inflammatory response during the metabolic processes that follow ingestion. They are not inclusive. It is important to note that small amounts foods which up-regulate inflammatory reactions will not nullify the effect of a mainly anti-inflammatory meal. An example would be a packet of sugar and pat of butter on a large bowl of oatmeal. On the other hand, foods that down-regulate inflammation may lose some or all of their benefit if they are prepared incorrectly, such as battered, deep-fried vegetables.

In part one, we identified the five major dietary causes that promote an imbalance favoring an excessive inflammatory response. Four of them:

1. **too much saturated fat** (and the related partially hydrogenated family),[1]
2. **too many refined carbohydrates** (including sugars)[1] and
3. the dietary ratio imbalances of **omega-6/omega-3 oils**[2] and
4. **sodium/potassium**[3] - are well-known.

However, energy imbalances that cause body-fat accrual are often overlooked as a cause of systemic inflammation.

Foods Generally Considered Pro-Inflammatory

American cheese, bacon, bologna, bratwurst, brownies, (white) breads - including buns, rolls and bagels, butter, cake, candy, cereals,* cheese (American, cheddar, creamed, gouda, jack, mozzarella, provolone, Swiss) cookies, corn chips, corn syrup, crackers*, cream, croissants, corn chips, Danish, doughnuts, egg rolls, French fries, French toast, (deep) fried foods, fruit juices, granola,* hamburgers, hash browns, honey, hot dogs, ice cream, jam/jelly, margarine, molasses, muffins, noodles,* onion rings, pancakes, pastrami, pepperoni, pie, pickles, pita bread,* pizza, pasta,* popcorn, potato chips, pretzels, puddings, relish, ribs (beef or pork), rice (white), salami, sausage, sherbet, shortening, sodas/soft drinks, syrup, tortillas (flour), tortilla chips, waffles, whipped cream, whole dairy.

**Unless 100% whole grain and high fiber.*

Foods Generally Considered Anti-Inflammatory

Acai, amaranth, anchovies, apples, apricots, arugula, artichokes, asparagus, avocado, bananas, beans (green beans, black beans, kidney beans, garbanzo beans, pinto beans, lima beans, soy beans), bean sprouts, beets, berries (blackberries, blueberries, boysenberries, goji berries gooseberries, raspberries, strawberries) bok choy, broccoli, brussels sprouts, cabbage, canola oil, cantaloupe, carrots, cauliflower, celery, cherries, cranberries, cucumbers, dairy (nonfat), eggplant, endive, gooseberries, grapes, grapefruit, herring, honeydew, kale, lemons, lentils, mackerel, mango, mangosteen, millet, mushrooms, mustard greens, nectarines, noni, nuts - raw (almonds, Brazil nuts, cashews, chestnuts, filberts, hazelnuts, macadamia, pecans, peanuts, walnuts), oats, okra, olive oil, onions, oranges, papaya, parsnips, pears, peas, peaches, peppers (bell and hot), persimmons, pineapple, pomegranate, plums, poultry (no skin), prunes, pumpkin, quinoa, rhubarb, rutabaga, salmon, sardines, scallions, seeds (flax, poppy, pumpkin, sesame, sunflower), spices (cinnamon, cayenne, garlic, ginger, green tea, parsley, pepper, nutmeg, oregano, rosemary, turmeric), spinach, squash (butternut, crook neck, summer, winter, zucchini), sweet potatoes, tomatoes, trout, tuna (water-packed), turnips, water chestnuts, watermelon, wild game, yams.

It appears that simply eating too much, too often may be the most powerful factor in the promotion of an **exaggerated inflammatory response**.[4] For example, 444 teenagers (249 boys and 195 girls) were studied for the purpose of evaluating **how fitness can prevent cardiovascular disease**.[5] They were divided into four groups: normal body-weight and physically fit; normal weight/unfit; overweight and fit; and overweight/unfit. Testing revealed serum levels of C-reactive protein were *not* associated with fitness level. Rather, CRP corresponded to the subjects who were overweight:

- Twenty-three percent of the normal-weight, fit teens had CRP elevations.
- Twenty-four percent of the normal-weight, unfit teens had CRP elevations.
- Fifty percent of the overweight, fit teens had CRP elevations.
- Fifty-six percent of the overweight, unfit teens had CRP elevations.

Body weight had a much greater effect on systemic inflammation than the degree of fitness did. The dietary imbalances we discussed in part 1 yield a food pattern (fatty, starchy, sweet and salty) that promotes overeating by triggering neurochemical responses that hyperstimulate our appetites. We prefer to eat these foods together; therefore, they drive inflammation by both their individual biochemical properties and the overlooked effect of hunger amplification during consumption.

For example, consider how a plate of celery and carrot sticks affects your appetite compared to the same plate filled with fresh-baked chocolate chip cookies. When you start eating the celery and carrot sticks, after a few you've had enough. But with cookies (each of which has 10-20 times

more calories than the celery/carrot sticks), the more you eat, the more you want until you're really full. And what do we get when we eat chocolate chip cookies? Refined starch, sugars and saturated fat.

Although there is not a significant amount of sodium in chocolate chip cookies, my analysis of five brands/recipes revealed sodium/potassium ratios from 7:1 to 3:1, with an average of 5:1. The recommended daily allowance for sodium and potassium (2,400 mg and 3,500 mg, respectively) works out to a 1:1.5 ratio.

Finally, chocolate chip cookies are not a significant source of polyunsaturated fats. However, the small amounts they do have yield a 10:1 omega-6/omega-3 ratio. That is not as bad as the 15:1 ratio the average American consumes, but is still high enough to **promote inflammatory marker increases and symptoms in some conditions**, such as rheumatoid arthritis and asthma.[6]

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Why Diets Are Failing Us

By: Peter Greenlaw and Dr. Dennis Harper

The first reason diets don't work is that we are living in a polluted world. Major studies conducted by Mt. Sinai Medical School and National Geographic have shown that our bodies are storing pollution, acid and impurities in fat cells. In these studies the participants had between 100 and 200 toxic chemicals in their blood and urine. Every single person who was tested.
In another study done in conjunction with the American Red Cross and the Environmental working group the study examined the cord blood from new born babies. In every baby tested they found an average of 287 toxic chemicals including, mercury, iodine, scotch guard, Teflon, and gasoline by-products. Every single baby… Can you imagine how toxic we are?

More evidence why diets just cannot work anymore

Quote from a new book "The New American Diet" page 6, Quote "Even the Endocrine Society, the largest organization of experts devoted to research on hormones and the clinical practice of endocrinology, recently reported that 'the rise in the incidence in obesity matches the rise in the use and distribution of industrial chemicals that may be playing a role in a generation of obesity, suggesting Endocrine Disrupting Chemicals (EDC's) may be linked to this epidemic'."
"Obesogens are thought to act by hijacking the regulatory systems that control body weight," says Frederick von Saal, Ph.D., curator's professor of biological science at the University of Missouri. No wonder traditional diet advice doesn't work!

USA Today March 16, 2010 page 7d quote "Physicians know they're on the front lines in the fight against obesity, but many say they don't have the staff able to help patients with weight loss, according to a survey of 290n primary-care physicians by Harris interactive. 72% say no one in their office has been trained to deal with weight problems." They go on to say "What came through in the survey is that is that physicians don't have many of the tools they need to help people succeed."

Government statistics show that 34% of US adults are Obese, which increases their risk of heart disease, type 2 diabetes, many types of cancer and other diseases. In a separate telephone survey of 1,002 adults in the USA, also by Harris interactive, only about one-third of those are obese – roughly 30 or more pounds over a healthy weight – say they have been told by a health care professional they are too heavy. Of the patients who were told they were obese, most 90% were advised to lose weight, 36% say the medical professional never discussed ways to achieve a healthier weight." We obviously have a real problem with awareness, and solutions, even in the medical community despite the fact that Obesity contributes to over 60 known diseases.

More evidence on the why we are losing the battle against weight gain!
Dr. Paul Baille Hamilton M.D. (educated at Oxford in England) in her book "Toxic Overload" Quote " When researching my first book, which examines the effects chemicals have on our weight, I was absolutely staggered to learn the extent to which toxic chemicals appear to be able to damage virtually every part of our musculoskeletal system. What appears to be happening is that our natural slimming system is being poisoned by the toxic chemicals we encounter in our everyday lives, and this damage is making it increasingly difficult for our bodies to control their weight. The end result is that we gain weight in the form of fat and not muscle, as chemicals tend to cause muscles to shrink and body fat to accumulate."

Another recent study stated that the human body is now evolving to deal with these chemicals. Our immune system is just not capable of dealing with these chemicals. In this study they say that unlike the old popular belief that we are born with a certain number of fat cells and that old belief is now changing. The latest evidence shows that they human body is actually making new fat cells to enrobe these chemicals and toxins (obesogens).

Obesogens from the book "The New American Diet" page 3 "Simply put, obesogens are chemicals that disrupt the function of our hormonal system, leading to weight gain and many of the diseases that curse the American populace. They enter our bodies from a variety of sources-from natural compounds found in soy products, from artificial hormones fed to our animals, from plastic pollutants in some food packaging, from chemicals added to processed foods, and from pesticides sprayed on our produce. They act in a variety of ways-mimicking human hormones such as estrogen, blocking the action of other hormones such as testosterone, and, in some cases, altering the functions of our genes and essentially programming us to gain weight." This is one of the main reasons over 75% of America is now overweight and recent reports from a documentary on the Learning Channel estimates that over 1 million Americans now weigh over 500 pounds. And, yet we have diets and diets and more diets. There are so many new approaches everyday as we get bigger and bigger. We keep thinking we are just over-eating and that is the only reason. Hopefully you can already see we have a new set of problems to deal with. Diets do not and can-not deal with these obesogens. Isn't something terribly wrong with this picture?

What is happening to us as a society and as a world? We are relying on the body to deal with this toxic overload of chemicals and toxins that it was never intended to deal with. And, the end result is that we are over-weight, stressed out and getting sicker and sicker by the day.

The Liver

Specifically, the liver is overloaded and it is the major way that the body deals with the pollution, waste and acids that are flooding our bodies. Toxins: Why You Should Cleanse for Life December 12, 2009 by Isagenix Nutritional Sciences Long-term protection from toxins can be achieved by living a nutritional cleansing lifestyle. As studies now point out every day we're continually exposed to toxins in the food we eat, the air we breathe, the water we drink, and the items we touch. Learning more about these potentially harmful chemicals can be critical for making decisions to protect long-term health. As with any subject, toxins are best understood through a little history. Toxins—or xenobiotics—have always been part of the natural environment. Many of them are made by plants, bacteria, and animals as defenses to keep predators at bay. The greater the abundance of toxins in a species, the more likely they will survive.

This natural arms race has produced millions of different kinds of toxins including venoms and poisons. Human exposure to toxins also depends on how food is prepared. The use of fire was a novel way to deal with food toxins. Heat breaks down many plant and animal defenses. Another example was fermentation, in which microorganisms produce a food that is edible. As our ancestors improved upon their culinary talents, they were able to expand their palates. Humans would eventually enjoy a wide variety of foods spanning all parts of the world. As they did, new foods and food preparation techniques would introduce new toxins. Examples are the chemicals produced by heat, such as char, nitrosamines or acryl amide, which can each be carcinogenic. The act of living itself also comes to us at a cost. Toxins are produced within the human body from simply being alive day to day. Toxins may, at times, be used to battle foreign bacteria or viruses. These can cause harm as they work to protect the body, but after their job is done, they are detoxified through biochemical processes.

Modern World

In our modern environment, pollution and food processing has increased our toxic load considerably. Humans have added thousands of new chemicals that pollute our air and water. These toxins can often end up in our foods, not just in plants, but concentrated in the animals that we eat. Food is also laden with chemicals in form of pesticides, processing agents and artificial ingredients. Continual flow of pollutants into water sources increases our risk of exposure to toxins. As our bodies are endlessly exposed to toxins, the toxins can overwhelm the body's natural detoxification defenses. A slow accumulation of toxins in our bodies may eventually disturb our natural processes. It only adds to our toxic load when—in an age where portion sizes have grown out of proportion—we eat a lot more food than ever before. Most of the foods available are designed, not to support us nutritionally, but to appeal to the power of our taste buds. Our busy schedules have also made processed foods all the more convenient, adding to the waistline-expanding potential of sedentary lifestyles, and putting further burden on our bodies.

Human Body

The human body has had to adapt over the generations to removing varying toxic loads. Our bodies come equipped with powerful protections in forms of detoxification or cleansing systems. They are found throughout the body: in the stomach, the intestine, the liver and the kidneys. The liver is a primary detoxification organ, metabolizing thousands of different chemicals we're exposed to daily. Much of what we eat must pass through our livers. As the liver breaks nutrients down, it also metabolizes toxic substances. In most cases, these toxins are cleared from the blood, then eliminated through bile or urine. At other times, they can become stored in fat. In addition, each individual cell contains its own inherent protections from the daily stresses of simply living. These include powerful detoxification and antioxidant enzymes, which help maintain cellular integrity so that the cell may function appropriately.

Nutritional Cleansing

Our ancestors found ways to enhance many of the body's internal detoxification and cleansing systems. These nutritional cleansing methods, which have been around for thousands of years, are only now beginning to be understood. A common practice was the use of fasting along with herbal teas or special botanicals. The reduced food intake would allow the body to purify itself through rest and renewal. Botanicals such as aloe gel, licorice root and ashwaghanda root contain bioactives that encourage detoxification within the liver and in the individual cells. Nutritional cleansing assists the liver, a primary detoxifier. Age-old traditions of nutritional cleansing have now been combined with modern technologies. It can be achieved by simple lifestyle changes such as choosing clean fruits and vegetables, drinking clean water, using non-toxic skin care and seeking out fresh air whenever possible.

"The body stores these impurities in pre-existing fat cells and it creates fat as the impurities continue to enter the body. The fat cells enlarge and shrink to accommodate the fat storage needed. Additionally, our bodies will hold water due to inflammation which dilutes these substances."

Grain Brain: The Surprising Truth about Wheat, Carbs, and Sugar--Your Brain's Silent Killers

David Perlmutter, MD, FACN, ABIHM is a Board-Certified Neurologist and Fellow of the American College of Nutrition who received his M.D. degree from the University of Miami School of Medicine where he was awarded the Leonard G. Rowntree Research Award. Dr. Perlmutter is a frequent lecturer at symposia sponsored by such medical institutions as Columbia University, the University of Arizona, Scripps Institute, and Harvard University. He has contributed extensively to the world medical literature with publications appearing in The Journal of Neurosurgery, The Southern Medical Journal, Journal of Applied Nutrition, and Archives of Neurology. He is the author of: The Better Brain Book and the #1 New York Times Bestseller, Grain Brain. He is recognized internationally as a leader in the field of nutritional influences in neurological disorders. Dr. Perlmutter has been interviewed on many nationally syndicated radio and television programs including 20/20, Larry King Live, CNN, Fox News, Fox and Friends.

In his latest book, neurologist Perlmutter (The Better Brain Book) declares war on a common foodstuff, attributing a bewilderingly wide assortment of maladies to the consumption of gluten, a substance found in bread and other stock foods. Contrasting modern humans against idealized humans of the distant past, Perlmutter concludes that the former, whose average life expectancy at birth is about twice that of their Paleolithic ancestors have gone off the proper track. He addresses the churlish objection that gluten has been part of the human diet for many millennia by firmly asserting that recent changes to crops have transformed a once-safe food into a terrible scourge. The book features health advice, a number of gluten-free recipes, and details on some relevant case studies. Lauded by such nonconsensus pundits as Mehmet Oz and William Davis, Perlmutter offers readers a comfortably simplistic model for thinking about carbs.

Obesity, Back Pain Have Most Impact on Early Osteoarthritis Patients

November 1, 2012
Wesseling J, Welsing PM, Bierma-Zeinstra SM, *et al* Impact of self-reported comorbidity on physical and mental health status in early symptomatic osteoarthritis: the CHECK (Cohort Hip and Cohort Knee) study Rheumatology (Oxford) First pubhlished online Oct 23,2012. doi: 10.1093/rheumatology/kes288

Patterns of diet and physical activity, major drivers of morbidity and mortality, are contingent on people's feasible opportunities to pursue healthy behaviors.

Of all possible comorbidities that can trouble people who have early symptomatic osteoarthritis (OA), obesity and back disorders have the greatest negative impact on physical well-being and pain. This is the outcome of ten years follow-up in the CHECK (Cohort Hip and Cohort Knee) Study, launched in the Netherlands by the Dutch Arthritis Association.

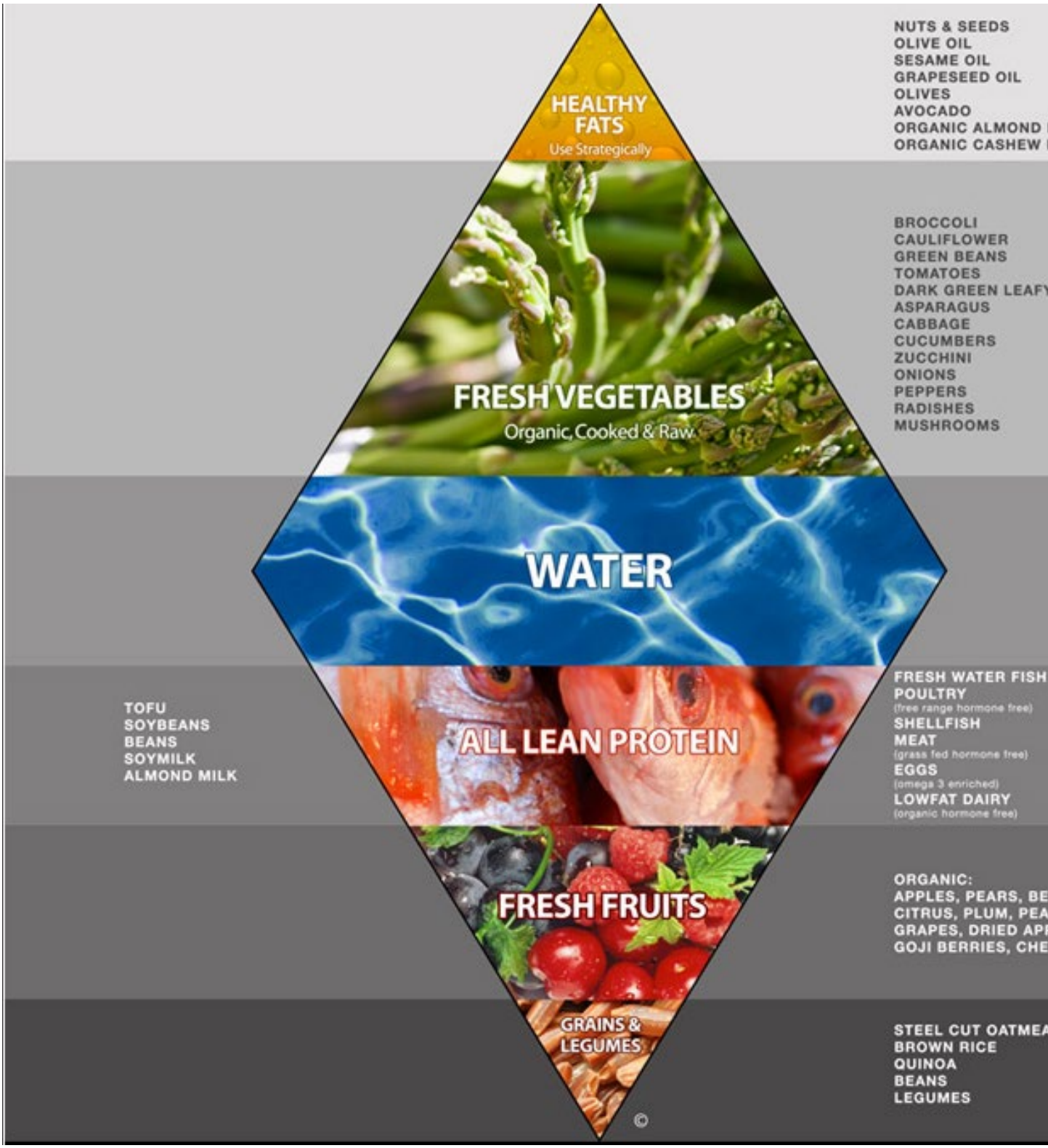
As to mental status, the four comorbidities most likely to dampen the spirits of someone with early OA significantly were duodenal ulcer, thyroid disease, or chronic or migraine headache.

Primary Prevention of Cardiovascular Disease with a Mediterranean Diet

N Engl J Med 2013; 368:1279-1290April 4, 2013 DOI: 10.1056/NEJMoa1200303

In this trial, an energy-unrestricted **Mediterranean diet supplemented with either extra-virgin olive oil or nuts resulted in an absolute risk reduction of approximately 3 major cardiovascular events per 1000 person-years, for a relative risk reduction of approximately 30%,** among high-risk persons who were initially free of cardiovascular disease. These results support the benefits of the Mediterranean diet for cardiovascular risk reduction. They are particularly relevant given the challenges of achieving and maintaining weight loss.

CONCLUSIONS: Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events.



Designed by Dr. Robert Willix, CEO Cenegenics Boca Raton

2. Coordinate previous/existing health care with up-to-date imaging to provide the patient with the dignity of a proper diagnosis (4 R's).

- Recent MRI unless contraindicated, imaging the area(s) of concern (based on both clinician and patient input).
- Recent MRI of the portion of the spine that could serve as a potential "proximal" instigator of patient's more distal symptomatic area (Cervical spine MRI for patients with upper extremity symptoms, Lumbar MRI for pelvic and lower extremity symptoms, etc.).
- Review all existing clinical notes and prior imaging studies and correlate with updated imaging studies.
- Reassure the patient that their direct participation and understanding is key if successful regenerative therapy is to be achieved. The patient's ideas, concerns and expectations for their personalized regenerative medicine therapy are addressed.

3. Collate all prior medical and surgical history.

4. Correlate pharmaceutical history.

A). NO NSAID'S- non steroidal anti-inflammatory drugs!

Most patients present with **"De-generative"** (bad-destructive) inflammation and PRP promotes **"Re-generative"** (good-constructive) inflammation.

The inflammatory response

- Following injury to the soft tissues and moveable joints of the musculoskeletal system including the spine there is a six week 'window of opportunity' for maximum healing that, once passed, without regenerative cellular medicine techniques may never be revisited.
- If there is after-effect loss of normal joint movement (due to partial dislocation) that is not restored during this early 'healing phase,' there is usually a degree of resulting permanent impairment.

- Increasingly, health care providers recognize the importance of manual (hands-on) therapy to re-set, re-align and restore lost motion in injured joints in order to avoid long term disability.
- The **"good"** inflammatory response begins 3 days after injury (lasting 4 days) with a release of **"pro"** inflammatory chemicals into the extracellular fluid and initiates **"positive"** healing (constructive, organized healing as opposed to destructive, disorganized healing).
- By interfering with and derailing this **"good"** regenerative inflammation, NSAID's prevent the key initiation phase necessary for optimum healing.
- Sources of these important **"positive"** inflammatory mediators (the most important of which are histamine, prostaglandins, and cytokines) are injured tissue cells, lymphocytes, mast cells and blood proteins. PRP injection therapy can **"rekindle"** this process if the window of opportunity for natural healing has been missed.
- The presence of these **"positive"** chemicals promote and further the **"positive"** reactions to short term **"regenerative"** inflammation, in which the patient may experience post-injection redness, heat, swelling, and pain.
- In our PRP protocol we treat this brief period of discomfort with non interfering opiods (Tramadol- Ultram) and/or Stadol nasal spray.

Anti-inflammatory Drugs- Interference with the inflammatory response

- Anti-inflammatory drugs block or suppress the **"regenerative"** inflammatory response by preventing or reducing the appearance of **perceived "adverse"** reactions to the irritant/injury (although we now know that the short term pain and other unpleasant symptoms that immediately follow injury are actually the result of "positive" and constructive healing processes that should not be derailed with NSAIS's).
- Diseases such as asthma, arthritis, organ transplants, and surgical trauma, for example, are treated with non-steroidal or steroidal anti-inflammatory agents, often with numerous **unwanted side effects**.
- Aspirin and other anti-inflammatory drugs exert their analgesic effects by inhibiting prostaglandin synthesis, a necessary **"regenerative"** inflammatory mediator.
- Non Steroidal Anti-Inflammatory Drugs (NSAIDs) are medications which although having pain-relieving (analgesic) effects do so by reducing **"regenerative"** inflammation and when used over a period of time also interact with other important bodily functions (cardiac, pulmonary, neurological, gastrointestinal, etc.) as well as interfere with the action and metabolism of other drugs.
- The anti-inflammatory effects even after stopping the NSAID intake may continue to interfere with healing from a few days to several weeks.
- Non Steroidal Anti-Inflammatory Drugs (NSAIDs) are medications promoted as having pain-relieving (analgesic) effects in fact have the effect of interfering with the **"good"** regenerative inflammation necessary for wound healing.

Anti-inflammatory Drugs- Properties and side effects

- As stated above, the NSAIDs work by affecting certain chemicals in the body which promote **"regenerative"** inflammation; the prostaglandins.
- Unfortunately the same group of chemicals is involved in the stomach, and so the NSAIDs tend to cause indigestion, and may even cause duodenal or stomach ulceration.
- As a result of this side-effect they cannot be used in patients with a history of peptic ulcer, except in exceptional circumstances, under close medical supervision. Also they would rarely be used and, if used, only with extra care, in patients with heartburn or indigestion.
- In general, the more effective a NSAID is at reducing inflammation, the more likely it is to cause indigestion. Often they will be prescribed along with additional drugs to decrease the risk of ulceration. There is even one medication that contains both components in one pill (yet another example of the exceedingly common practice when encountering a side effect of one drug; instead of stopping the offending drug, the typical response is to prescribe a second drug to mask the side effect of the first one).
- The reported "advances", in which certain NSAIDs were said to be more specific in dealing with inflammation and less likely to irritate the digestive (gastro-intestinal) system, have not only been refuted, but as in the case with .
- The drugs vary in strength and side effects. Usually, as with other medications, the more *effective* they are, the more *side-effects* they are likely to have. Aspirin, which originated from willow bark, has been around for a long time and is in many people's medicine chests. This is an anti-inflammatory analgesic. Most NSAIDs also reduce the temperature in someone with a fever.
- Of the medications in this group, the one in widest general use is Ibuprofen (Motrin).

Thus, in our protocol we **eliminate all NSAID's**: as stated above, these drugs achieve pain reduction by inhibiting the body's immune system from being able to mount the **"regenerative"** inflammatory process necessary for wound healing, and well as adversely interacting with other drugs and bodily functions.

The peer reviewed world literature documents these facts:

- "It is known that there is **long term risk of using nonsteroidal anti-inflammatory drugs (NSAIDs) in patients with prior myocardial infarction".**
- On September 30, 2004, Merck voluntarily **withdrew rofecoxib from the market because of concerns about increased risk of heart attack and stroke** associated with long-term, high-dosage use. Merck withdrew the drug after disclosures that it withheld information about rofecoxib's risks from doctors and patients for over five years, resulting in between 88,000 and 140,000 cases of serious heart disease. Rofecoxib was one of the most widely used drugs ever to be withdrawn from the market. In the year before withdrawal, Merck had sales revenue of US$2.5 billion from Vioxx.
- "Nonsteroidal anti-inflammatory drugs, such as Aleve (naproxen) and Advil (ibuprofen), appear to impair **the effectiveness of selective serotonin reuptake inhibitors (anti depression drugs),** such as Prozac (fluoxetine) and Celexa (citalopram)".

- "That **cardiovascular safety cannot be assumed for any of the nonsteroidal anti-inflammatory drugs** commonly used to treat musculoskeletal pain, according to a large meta-analysis".
- **"The regular use of nonsteroidal anti-inflammatory drugs (NSAIDs) is associated with higher odds of erectile dysfunction, a cross-sectional study showed".**

B). NO STEROIDS!

1. Strong evidence has demonstrated that corticosteroid injection is beneficial in the short term for treatment of tendinopathy, *but is* ***worse than are other treatment options in the intermediate and long terms*****.**
2. Use of corticosteroid injections … poses a clinical dilemma because consistent findings suggest good short-term effects but, for instance, tendinopathy does not have an inflammatory pathogenesis.
3. *Systematic review challenges* ***continued use of corticosteroid injections by providing strong evidence that they are worse in the long term than are most conservative interventions for tendinopathy.***
4. A recent larger double-blind randomized controlled trial (n = 100) comparing PRP with corticosteroid injections found a statistically and clinically significant difference in disease specific quality of life in pain scores favoring the PRP group.
5. Interestingly, the **PRP group progressively improved** at 1 year compared with the steroid group, which declined after an initial short-term improvement, suggesting that progressive healing may be responsible for clinical improvement in the PRP subjects.

Steroidal Anti-Inflammatory Drugs

- Prednisone and prednisolone are steroidal antiinflammatory drugs, used to treat a wide variety of conditions such as autoimmune diseases, ulcerative colitis, asthma, dermatological disorders, Crohn's disease, tendinitis, bursitis, to prevent organ transplant rejection, and in many chemotherapeutic regimens.

Thus, our regenerative medicine protocol calls for **excluding steroids**, either injected or orally/nasally administered. Steroids when viewed under the microscope are crystals in solution that when injected become emboli (particles that block blood vessels) reducing pain by infarcting ("killing") tissue. The literature is clear; that steroid's "positive" pain reduction is only short term and that the embolized tissue eventually becomes more painful due to its destruction by the disruption of blood flow caused by the crystalline steroid injection.

Extensive meta-analysis of the existing literature has **failed to show that steroids are efficacious in the healing process**, instead demonstrating only a short lived respite from pain often accompanied by subsequent atrophy and necrosis. A paper by Dr. Peter McMahon presented in the MSK interventional lecture on Monday at the RSNA (Radiology Society of

North America) 2010 showed how most injectible steroids (depo-medrol, kenalog, etc.) are "particulate preparations" comprised of substantial sized crystals, and that they have a propensity to aggregate into even larger size particles that can then embolize (block) the arterioles in and around the injection site producing unintended infarction and necrosis. Only dexamethasone sodium phosphonate (DSP) remains a true non particulate fluid after injection (explaining why DSP is shorter acting than its particulate cousins that are "longer acting" as they require enzymatic breakdown to become active).

As an aside, we should also be using local anesthetics free of methylparaben (a preservative in injectible anesthetics) as methylparaben induces crystallization of our local anesthetic solutions, which could potentially embolize arterioles in the injection site. We also know that lidocaine (lower in molecular weight) is less cytotoxic than marcaine and bupivicaine when used for local pain control for these regenerative medicine procedures, and that procaine, an ester, is prone to aggregate more so than the amide local anesthetics, such as lidocaine.

Side effects of Steroid Injection

Unlike anabolic steroids, sometimes misused by athletes, injectable steroids such as cortisone are used to treat joint inflammation from injury and arthritis, chronic back and neck pain and even acne. The injection and the steroid drugs can induce side effects, the severity of which dependent upon the location and amount of steroid injected as well as the health status of the patient.

- **Infection**

  Used for their anti-inflammatory properties, injected steroids can block the immune response at the injection site and set the stage for infection, according to American Orthopaedic Society for Sports Medicine. The procedure for injecting steroids involves inserting a fine needle into a joint or muscle, providing a chance to introduce bacteria into the body. Symptoms indicative of infection including fever and swelling, pain or redness at the injection site may require antibiotic treatment.

- **Increased Pain at Site**

  The pain from the steroid injection can be minimized if the doctor numbs the area to be injected first. Despite this, some people report experiencing an exacerbation, or worsening of their pain syndrome for hours to days following the procedure, according to Arthritis-treatment-and-relief.com. This pain, sometimes referred to as a flare, is caused by the hardening of the steroid upon injection into the body.

- **Systemic Effects**

  The term systemic refers to the effects generalized throughout the body, which steroids are capable of soliciting. Most notable are the immediate increase of blood pressure and blood sugars, according to NYU Langone Medical Center. These side effects are of concern in those with hypertension, or high blood pressure and diabetes. According to Sportsmed.org, these systemic effects are temporary but should be monitored for 24 to 48

hours after the injection. Facial flushing and personality changes have also been observed with steroid injection.

- **Vasovagal Reaction**

  Reactions to the injection procedure could include a type of fainting, medically known as a vasovagal reaction. Similar to the physiological effects of someone holding their breath for an extended period of time, this condition results in decreased blood pressure, heart rate and respiratory rate and can lead to shock and death if not reversed immediately.

The peer reviewed world literature documents these facts about steroid injection:

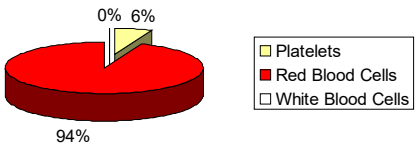
- "Consistent findings between many high-quality randomised controlled trials that **corticosteroid injections reduced pain in the short term** compared with other interventions, but **this effect was reversed at intermediate and long terms**".

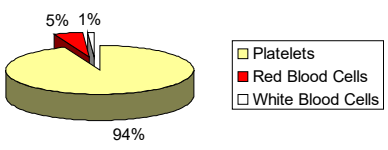
- Corticosteroid injections ease the pain of tennis elbow **short term but may worsen it long term**, according to a meta-analysis.

- "Even short courses of glucocorticoids (steroids) in conditions such as lupus, rheumatoid arthritis, and many other diseases can be associated with the development of **osteonecrosis (bone death),** a researcher cautioned".

5. Consummate overview of regenerative injection therapy (RIT) in sync with patient's existing health care regimen (PRP therapy is 'in addition to', not 'instead of' the patient's existing 'patient specific' health care regimen).

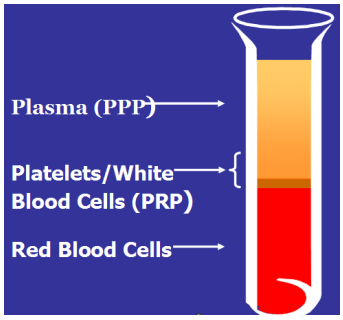
Biocellular Regenerative Therapies (BRT's) are emerging as a clear alternative to more traditional modalities, with less risk and morbidity, and excellent outcomes. **Platelet Rich Plasma (PRP) Prolotherapy** is one such BRT which, by definition, is composed of autologous (self) blood with concentrations of platelets above baseline levels, containing at least seven growth factors.





Preparation of PRP begins with venipuncture and subsequent collection of a product-specific volume of autologous whole blood from the patient into a syringe containing an anticoagulant, typically at the point of care. **Centrifugation** separates the whole blood into **three layers:**

- **RBCs** (bottom layer, specific gravity = 1.09),
- **Platelet -poor plasma** (top layer, specific gravity = 1.03), and
- **Platelet concentrate** that contains RBCs (middle layer, specific gravity = 1.06).



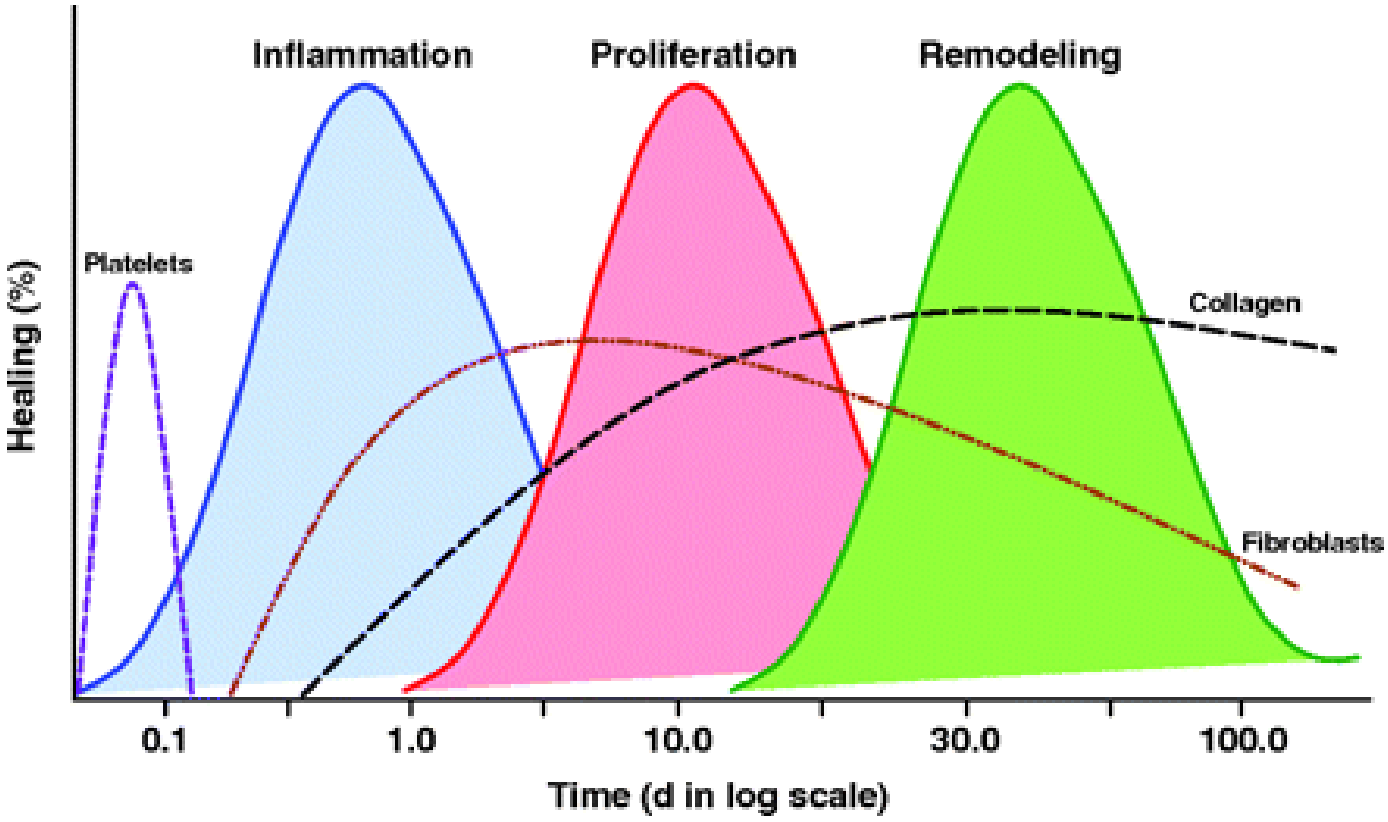
Our centers utilize highly concentrated (4-6 times and above) Platelet Rich Plasma obtained according to certified state of the art techniques. One such technique was perfected by Dr Noel Peterson in Portland, Oregon. This protocol has been accepted by our institutional review board (IRB) of the International Cellular Medicine Society IRB and our Medical Director has been personally certified by Dr. Peterson. This method produces therapeutic volumes of highly concentrated platelet rich plasma in a safe, sterile, time-efficient, reliable and economical procedure. prpconsultants-subscribe@yahoogroups.com

In addition, we utilize the **Emcyte Company's** platelet rich plasma point of care therapy with Pure PRP®. Pure PRP™ is a platelet rich plasma preparation that contains highly concentrated platelet growth factors with no red blood cells. Pure PRP® is also unique because it is the only PRP system that can be processed with or without neutrophil granulocytes. The platelet and growth factor concentrations are 7 to 9 X baseline and the yields range from 80-98%. The collected PRP sample is 6mL from a 60mL sample of anticoagulated whole blood. Pure PRP® is the absolute solution to meets all clinical demands in a medium that is suitable for active wound repair.

Pure PRP® provides high concentrations of platelet & growth factors in a pure plasma suspension. It has a no red blood cells which increase PRP viscosity making it more difficult to inject. Red blood cells in PRP have also been reported to cause pain. The polymorphonuclear cell family (PMNs) includes the body's most abundantly occurring granulocyte known as neutrophils. These granulocytes, in abundant & sustained doses release cytokines, which can amplify inflammatory reactions by several other cell types. This inflammation is needed for active wound repair, but in some cases is undesirable. Pure PRP® is the only PRP system that can be processed with or without neutrophil granulocytes, providing our physicians with their choice of active components needed for the care of their patients.

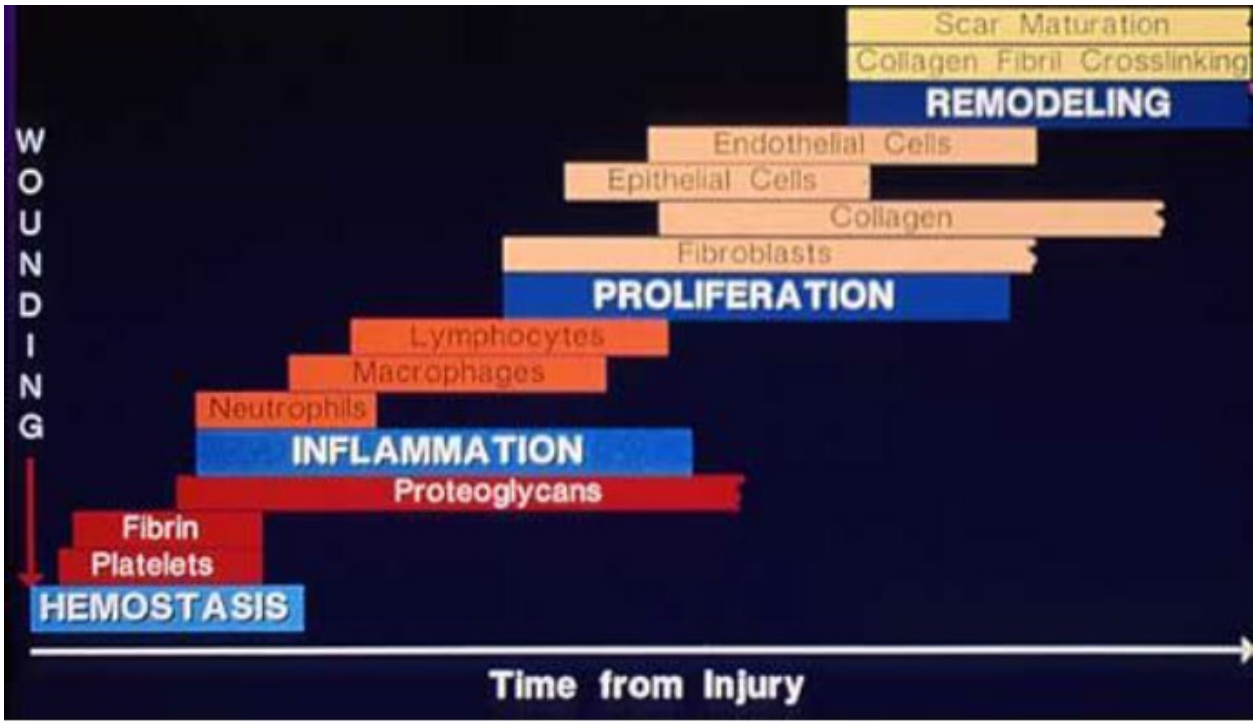
PRP Prolotherapy stimulates musculoskeletal healing in same manner as **Dextrose Prolotherapy**, but also provides growth factors to the tissue directly (similar to "adding fertilizer"). PRP growth factors and cytokines aid in wound healing and tissue repair while inhibiting inflammatory processes in osteoarthritis and is useful when **Dextrose Prolotherapy** levels out or if there is excessive degeneration or tendinosis. Chronic inflammation uses up the local repair (stem) cells which is why we may need to add repair cells (CD34 hematopoietic stem cells contained in PRP) to that area.

The physiology and time course of wound healing is depicted in the diagrams below. The first diagram shows the wound healing cascade, outlining intricate process of three overlapping phases of healing: **inflammation, proliferation, and remodeling.**



Biology of PRP

- The first step of the healing process is **clot formation and platelet activation.** After platelet activation, many growth and differentiation factors are **released from the alpha-granules**, which are storage units found in platelets.
- **Ninety-five percent of the existing factors are released within 10 minutes of clot formation**, whereas the rest of the growth factors are released as they are formed over several days.
- In vivo and in vitro research also suggest that PRP induces **over expression of additional endogenous growth factors** beyond what is contained within the platelet concentrate



Our centers utilize the Sentry Air Systems' line of Clean Room Hoods (Laminar Flow Hoods) that are HEPA or ULPA-filtered positive-pressure environments designed for applications that require a sterile work space. Sentry Air offers ISO Class 5. These Clean Rooms utilize a powerful fan to draw in ambient air and purify it with high-quality filtration media to provide exceptionally clean, purified airflow inside the hood. These bench top systems are used for a wide selection of applications, including Medical Applications like Stem Cell Therapy Processes.

Once the patients undergo clinical and imaging evaluation and agree with the method of therapy and condition to be treated, informed consent forms are signed.

Physician qualifications in our centers include credentialing by the **American Association of Orthopedic Medicine (AAOM)** for regenerative injection therapy (RIT) as well as certification by the **International Cellular Medicine Society (ICMS)** to perform cellular medicine therapies.

Our Medical Director serves on the boards of the both the AAOM and the ICMS, as well as serving on the **Institutional Review Board (IRB) of the ICMS**.

The **International Cellular Medical Society (ICMS)** asserts that a need exists to create standards for platelet rich plasma (PRP) protocols, preparations, techniques and tracking. We believe that physician-led organizations will serve the needs and interests of both patients and physicians toward achieving the best outcomes. In order to advance PRP in particular (and autologous cellular medicine therapies in general), we have developed these guidelines to assist physicians in performing safe therapies, promote patient education, encourage robust clinical research and begin to define the scope and anticipated effects of these procedures

With regard to basic Physician Training, our Medical Director has completed a residency in Radiology with fellowship training NMSK (neuro-musculo-skeletal system), Ultrasound and Interventional Radiology. This assures that our physician has been instructed in obtaining a proper history, performs a detailed neuromusculoskeletal examination, considers appropriate differential diagnoses, understands the usual treatments for the common diagnoses and has the ability to consider alternative, complimentary or advanced treatment options.

With regard to PRP training, our Medical Director attends and administers international training courses on the preparation and use of PRP, including the appropriate indications and contraindications as well as recognition and management of untoward outcomes and use of proper pain management strategies for peri and post procedural pain control.

With regard to injection guidance training, our Medical Director has training and expertise in the appropriate choice and use of guidance technology (i.e. Ultrasound, CT, fluoroscopy, ect.) through extensive residency training, fellowship training, post-graduate continuing medical education and clinical proctoring (peer to peer training)

Our clinics provide the ICMS a self assessment of compliance to the ICMS clinical, laboratory and patient record standards.

COMMON CONDITIONS TREATED WITH PRP

1) Sports Medicine
2) Pain Medicine
3) Disorders of the shoulder including bursitis and rotator cuff tears
4) Tendonitis of a variety of tendons including:
    - tennis elbow and
    - Achilles “tendonitis”
5) Heel spur syndrome
6) Muscle tears, sprains, trigger points
7) Meniscus tears of the knee
8) Mild to moderate degenerative arthritis of various joints
9) Disorders of the spine

WHO IS NOT A CANDIDATE FOR PRP?

1) Various blood diseases or bone marrow derived cancers such as lymphoma, etc.

2) Severe anemia and/or platelet count below 100,000 (normal is 150 to 350,000/micro liter)
3) Consistent use of NSAIDS (non steroidal anti-inflammatory drugs)
4) Cortisone injection at the treatment site within 6 weeks, or systemic use of cortisone
5) Active cancers
6) Active infections
7) Minimal alcohol intake
8) Coumadin, Plavix and high dose aspirin on patient by patient basis.

HOW LONG BEFORE RESULTS ARE SEEN?

1) This varies with the patient's age, the condition being treated, severity of the condition etc. Some results can be seen in as little as two weeks.
2) Patients to expect a roller-coaster effect.
3) Some patients report pain can abruptly leave as if a light switch were turned off

Post-Injection

1) Monitor for post-procedure complications (vaso-vagal most common)
2) Patients are given post-procedure instructions, precautions, and emergency contact information.
3) Protocols for immobilization and post-procedure activity allowed/encouraged vary widely. Future recommendations will be evolving as protocols are more widely accepted +/- studied.
4) Post procedure analgesic prescriptions are dispensed as needed. Avoid NSAIDs until the patient has healed, is pain free, has full function or has reached a plateau.
5) Contaminated areas are disinfected in between patients per OSHA guidelines.
6) The procedure is recorded in detail with a procedure note including: date, pre/post-procedure diagnosis, procedure title, performing physician w/wo assistants, anesthesia, brief indication of procedure, description of graft preparation, description of procedure including guidance and instruments.

Follow-up

1) Patients are generally re-examined 2-6 weeks after the procedure to follow pain, function, injection site and to discuss concerns and future course.
2) Patient response should be recorded using validated outcome measures.
3) Complications, response and all other pertinent data are entered in the ICMS tracking system.
4) Consideration for re-injection is a patient centered decision and made based on functional outcome. We do not endorse a specific number of injections at any site.

6. Complete patient registry.

PRP clinics will place predetermined patients treated with platelet rich therapy into a Registry for outcome and complication tracking:

a. Patients entered into the registry will receive email outcomes and complication surveys at the following intervals:
   - Day of procedure (baseline), 3, 6, 12 and 18 months after the procedure.

b. Our clinics will email the patient three times at each follow up interval. If the patient does not respond, then the clinic will alert the clinic to conduct phone based follow up.
   - Any affirmative answer to a complication question will initiate an adjudication process in which the clinic must determine the likelihood that the complication resulted from the procedure and the intensity of the complaint.

c. All data collected by the survey will be stored and managed by the ICMS for review and analysis and made available to clinics through a secure web reporting interface.

Platelet Rich Plasma: Historical Perspective

The application of PRP has been documented in many fields. First promoted by M. Ferrari in 1987 as an autologous transfusion component after an open heart operation to avoid homologous blood product transfusion, there are now over 5200 entries in the NCBI for PRP ranging in fields from orthopedics, sports medicine, dentistry, otolaryngology, neurosurgery, ophthalmology, urology, wound healing, cosmetic, cardiothoracic and maxillofacial surgery.

The initial popularity of PRP grew from its promise as a **safe and natural alternative to surgery**. PRP advocates promoted the procedure as an organically based therapy that enabled healing through the use of one's own **natural growth factors**. In recent years, scientific research and technology has provided a new perspective on platelets. Studies suggest that platelets contain an abundance of growth factors and cytokines that can affect inflammation, postoperative blood loss, infection, osteogenesis, wound, muscle tear and soft tissue healing. Research now shows that platelets also release many bioactive proteins responsible for attracting macrophages, mesenchymal stem cells and osteoblasts that not only promote removal of degenerated and necrotic tissue, but also **enhance tissue regeneration and healing**.

Musculoskeletal practitioners began using PRP for tendinopathy in the early 1990s. These early practitioners were primarily trained in the use of prolotherapy. The popularity of PRP grew as physicians began to see clinical results in concentrating a patient's own blood factors. The PRP procedure is significantly more complex and requires additional equipment to perform successfully, but many practitioners have seen a relatively more robust response, fewer treatments and improved tissue health compared to prolotherapy.

Platelet rich plasma (PRP) therapy is a new treatment that relieves pain by promoting long lasting healing of musculoskeletal conditions. This rapidly emerging technique is showing exciting potential with osteoarthritis of the knee, shoulder, hip and spine, rotator cuff tears, chronic plantar fasciitis, anterior cruciate ligament (ACL) injuries, pelvic pain and instability, back and neck injuries, tennis elbow, ankle sprains, tendonitis, and ligament sprains.

How does PRP therapy help?

The body's first response to soft tissue injury is to deliver platelet cells. Packed with growth and healing factors, platelets initiate repair and attract the critical assistance of stem cells. PRP therapy's natural healing process intensifies the body's efforts by delivering a higher

concentration of platelets. To create PRP therapy, a small sample of your blood is drawn (similar to a lab test sample) and placed in a centrifuge that spins the blood at high speeds, separating the platelets from the other components. The concentrated platelet rich plasma (PRP) is then injected into and around the point of injury, jump-starting and significantly strengthening the body's natural healing signal. Because your own blood is used, there is no risk of a transmissible infection and a very low risk of allergic reaction.

How long does it take?

The procedure takes approximately one to two hours, including preparation and recovery time. Performed safely in a medical office, PRP therapy relieves pain without the risks of surgery, general anesthesia, or hospital stays and without a prolonged recovery. In fact, most people return to their jobs or usual activities right after the procedure.

How often should this procedure be done?

Up to three injections may be given in a 6-12 month time frame, usually performed several weeks to a few months apart. You may, however, gain considerable to complete relief after the first or second injection.

What are the expected results?

Because the goal of PRP therapy is to resolve pain through healing, it could prove to have lasting results. Initial improvement may be seen within a few weeks, gradually increasing as the healing progresses. Research studies and clinical practice have shown PRP therapy to be very effective at relieving pain and returning patients to their normal lives. Both ultrasound and MRI images have shown definitive tissue repair after PRP therapy, confirming the healing process. The need for surgery can also be greatly reduced by treating injured tissues before the damage progresses and the condition is irreversible.

The current guidelines will focus on general principles of PRP use and its applications specifically to musculoskeletal care.

Will disruptive innovations cure health care? **Harvard Business School, Boston, USA.**

It's no secret that health care delivery is convoluted, expensive, and often deeply dissatisfying to consumers. But what is less obvious is that a way out of this crisis exists. Simpler alternatives to expensive care are already here--everything from $5 eyeglasses that people can use to correct their own vision to angioplasty instead of open-heart surgery. Just as the PC replaced the mainframe and the telephone replaced the telegraph operator, disruptive innovations are changing the landscape of health care.

But established institutions--teaching hospitals, medical schools, insurance companies, and managed care facilities--are fighting these innovations tooth and nail. Instead of embracing change, they're turning the thumbscrews on their old processes--laying off workers, delaying payments, merging, and adding layers of overhead workers. Not only is this at the root of consumer dissatisfaction with the present system, it sows the seeds of its own destruction.

The history of disruptive innovations tells us that incumbent institutions will be replaced with ones whose business models are appropriate to the new technologies and markets. Instead of

working to preserve the existing systems, regulators, physicians, and pharmaceutical companies need to ask how they can enable more disruptive innovations to emerge. If the natural process of disruption is allowed to proceed, the result will be higher quality, lower cost, more convenient health care for everyone.

INFORMED CONSENT
FOR INJECTION THERAPY

Neural Therapy Homeopathic PRM Mesotherapy
Trigger Point Therapy Joint Injections

I, _____(print name), understand that this procedure is not guaranteed to relieve my pain, partially or totally. I also understand that there are potential complications which include increased pain, numbness, scarring, infection, abscess, weakness, and other disability. There is the possibility of complications due to the injection of anesthetic, drug reactions, or other factors, which may involve other parts of your body, including the possibility of brain damage, death, heart attack and stroke. I understand that Dr. David Harshfield M.D., will personally perform the entire procedure. I have received all the explanation that I wish to receive and I have been given the opportunity to ask questions. I understand the alternatives to this procedure. I have no further questions. I wish to have Injection Therapy.

I understand photographs may be taken during the procedure.

Patient Signature: _____Date: _____

Witness Signature: _____Date: _____

D.L. Harshfield M.D., M.S.

- **Board certified Radiologist with specialty training in:**
  - **NMSK (Neuromusculoskeletal Therapy)**
  - **Ultrasound**
  - **Interventional Radiology**
  - **Cellular Medicine**
- **Director of the College of Integrative Medicine- coimed.org**
- **Chairman of the Institutional Review Board (IRB) of the ICMS**
- **Advisory Board Member International Society for Cellular Medicine (ICMS)**
- **Board Member American Association of Orthopedic Medicine (AAOM)**