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V 1.0 created September 21, 2016.

Date (YYYY/MM/DD): _____

Last Name:_____ First Name: _____

Gender: _____ Birthdate(YYYY/MM/DD): _____ PHN: _____

Supportive injection therapy: overview and consent

Treatment of non-traumatic pains/ aches/ stiffness of tendons and joints without the use of surgery is generally speaking safer and associated with less risk when compared to surgical treatment. Surgery is generally reserved for situations in which non-operative treatment has proven to be insufficient or can be expected to lead to a poor outcome.

Non-operative treatment typically initially involves options such as activity modification, conditioning/ stretching/ strengthening, bracing/splinting when appropriate, physiotherapy, massage therapy, chiropractic treatment, non-steroidal anti-inflammatory medication (such as ibuprofen, naproxen, Celebrex), non-narcotic analgesic medication (Tylenol), at times mild narcotic medication (up to Tylenol #3; stronger narcotics such as hydromorphone are to be avoided for chronic non-cancer pain).

As an adjunct to this, strategic use of injection therapy can be helpful. At White Rock Orthopaedic Surgery Centre, injections are done under image guidance only to optimize accuracy. Ultrasound is used for all injections. For injections of the hip joint, additional x-ray is utilized. Of note, the Medical Services Plan does not provide for the use of imaging at point-of-care.

In order to minimize discomfort at the time of the injection, the skin is prepared with a local anaesthetic prior to injection. Even individuals who are fearful of 'needles' (injections) report that this method allows them to have injections around the joints or tendons without causing undue distress. A local anesthetic is mixed with the corticosteroid as well to help minimize irritation of the tissues.

A/ Corticosteroid injection.
Commonly referred to as 'cortisone shot'. This is the most commonly used injection modality, with utility in and/or around joints, tendons and other soft tissue structures. It is a means of suppressing inflammation, with typical reduction in swelling and pain. The medication is meant to have a localized effect limited to the area injected. This typically is effective for

approximately 6-8 weeks. Once the medication starts to 'wear off' (i.e. the level of medication in the injected area decreases to the point of no longer being effective), the pain may return or sufficient healing may have occurred for function to remain satisfactory, depending on the clinical scenario. For many patients the pain does not return immediately at the two months mark; rather, they may experience continued improvement, with symptoms of pain and dysfunction not returning until much later. For others, the pain returns as soon as the medication wear off at approximately two months.

Over the last few years, well over 1000 corticosteroid injections are administered through my office each year, at times several injections in one sitting, typically up to two sites. It turns out that many patients are extremely satisfied with this modality as treatment of troublesome joint and/or tendon pain, allowing them to carry on without the need to take excessive medication by mouth or to be subjected to surgery. Avoiding or postponing surgery typically is beneficial from a point of view of avoiding complications as well as from a point of view of not losing time needed for post-operative recovery and rehabilitation. These injections can be repeated from time to time. There is no set interval or maximum number of injections. In order for this to be practical, I typically consider up to two, possibly three, injections per year per site a reasonable guideline. If the source of pain is widespread, i.e. multiple joints/ tendons or with diffuse soft tissue involvement, corticosteroid injection may not be the most effective approach.

It is my observation that corticosteroid injections can be a cause of concern, with a fair bit of misinformation persisting. The following represents my view of the pertinent issues:

- *General side-effects.* Corticosteroid administration by mouth has well recognized side-effects. These are largely minimized by the use of local injection. Nonetheless, generalized effects are not completely avoided. It is not known precisely to what extent this is clinically relevant. Patients with diabetes may experience elevated blood sugar levels for several days afterward; a general sensation of 'feeling flushed' is not uncommon, lasting for a few days. The current formulation (Depo-medrol) has been used for well over 20 years in clinical practice, with many, likely millions, of these injections having been performed over a long period of time, largely by rheumatologists, family physicians, rehabilitation physicians, orthopaedic surgeons. It would be expected that any serious concerns would have emerged by now. In addition, any such risk would have to be weighed against the risks, costs, time commitment etc associated with alternative management options. It is my assessment that by and large in many situations the risk/benefit balance associated with corticosteroid injection is favourable. Of note, there is some indication that the clinical effectiveness is dose-dependent; although clinical side-effects may be less with a lower dose, there would be no net benefit if the dose is insufficient to bring optimum pain relief.
- *Possible detrimental effects to joints and tendons*. Injections into the substance of a tendon can lead to weakening and rupture. This must clearly be avoided. Ultrasound guidance is a valuable adjunct in ensuring injection in the tendon sheath, as opposed to into the tendon or too far away from the tendon to be possibly effective. The effect of corticosteroid injection on the health of articular cartilage is not fully understood. Ongoing untreated inflammation and swelling are thought to perpetuate and accelerate the process of degenerative osteoarthritis due to the effects of locally active mediators. On balance, it is my assessment that using a corticosteroid injection to suppress persistent inflammation and to facilitate ongoing conditioning within reasonable limits is preferable over leaving such an inflammatory state unaddressed.
- *Local effects*. It typically takes approximately three days before patients experience improvement in pain and swelling after a corticosteroid injection, occasionally it may

take up to a few weeks. Approximately 90-95% of patients report significant improvement after corticosteroid injection. This is well short of 100%**, there is a 5-10% likelihood of not experiencing improvement.**

Initially, patients may experience increased discomfort after corticosteroid injection. It is my assessment that approximately **15-20% of patients experience significant pain after corticosteroid injection, at times rated as SEVERE.** For most, but not all, this settles in a day or two. The occurrence of increased pain cannot be predicted, this may vary for the same individual from injection to injection, even when administered at the same time in different locations.

Any time the skin barrier is violated, the risk of infection exists**. In my office, all injections are done in a CLEAN designated procedure room with positive pressure ventilation, under formal STERILE TECHNIQUE, including sterile draping of the ultrasound probe and the site to be injected. Such attention to detail minimizes the risk of infection.** After several thousand injections to date, no infection has been encountered. The risk of infection remains real nonetheless, with potentially severe life-threatening consequences. The risk of infection associated with any surgical procedure is many times higher than the risk of infection associated with a corticosteroid injection.

B/ Viscosupplementation.

The process of osteoarthritis of an aging joint involves the loss of normal joint cartilage, but also the loss of normal lubricating and shock absorbing properties of the joint fluid. Normal joint fluid is viscous, comparable to motor oil or syrup. As part of the osteoarthritic process, the joint fluid becomes more watery, due to a reduction in concentration of hyaluronic acid. Replacement of the hyaluronic acid has been available as a treatment modality for over twenty years, with some incremental improvements along the way, most notably the transition from animal-derived hyaluronic acid preparations to synthetic bacterial-fermentation derived products, such as Synvisc or Durolane. I favour the use of Durolane: small injection volume, single injection, large molecules, established track record.

The exact mechanism of the effect of viscosupplementation is not understood, it is more complex than simple replacement of hyaluronic acid. The effectiveness of viscosupplementation remains incompletely documented. It is fair to state that up to approximately 80% of patients with osteoarthritis can derive meaningful benefit from viscosupplementation. Conversely, **at least 20% of patients will not experience benefit from Durolane or Synvisc injection**. This modality is less effective if administered when the joint is actively inflamed. Concurrent administration of a corticosteroid to suppress inflammation at the time of viscosupplementation has been effective in my practice.

If viscosupplementation is effective, the effects are typically markedly more prolonged than after corticosteroid injection, with meaningful improvement in pain for an average of 8 months, with many patients reporting benefit up to one year.

For some patients, typically in the 45-years-and-up age group, this treatment modality has proven very effective, with a regularly scheduled yearly injection sufficient to maintain an active and productive lifestyle.

In order to minimize disappointment, based on the response rate of approximately 80%, as discussed above, I typically provide an initial corticosteroid injection to assess the potential utility of injection therapy. If the initial corticosteroid injection does not bring pain relief, I do not recommend viscosupplementation. On the other hand, good pain relief after a corticosteroid injection would be a favourable prognosticator when considering viscosupplementation.

Viscosupplements, although administered through injection, are considered medical devices from a regulatory point of view. As such, re-imbursement/ coverage by various insurance programs is not universal.
Side-effects include the risks as discussed above. Viscosupplements can evoke a significant tissue reaction, a so-called flare response, with severe pain even to the point of raising concerns about joint infection. This is much less commonly seen with modern products such as Durolane, compared to older animal-derived preparations. In my assessment, some increased pain after Durolane is noted after approximately 20% of injections, with severe pain in less than 5%.

C/ Platelet rich plasma ('PRP').
Harnessing the natural healing power of the body has received significant attention in the last two decades. Patients and physicians alike are looking forward to the day that meaningful regenerative treatment would be able to change the natural course of progressive age-related wear and tear of the joints and tendons. At present, the only practical application of such principles is the use of PRP. This involves taking a blood sample in the clinic, with processing in a centrifugation/ separation protocol, leading to a small volume of blood plasma rich in platelets. The blood platelets contain a host of factors which upon release stimulate and orchestrate various healing processes. Injection of PRP has been used for some 15 years in the treatment of tendonitis and related tendon problems. Although the initial data regarding effectiveness were derived from injections around the heel and elbow, the range of tendons injected has expanded markedly. In my experience, this has been most helpful in treatment of severe unrelenting pain around the point of the hip, after it has become clear that this only is transiently responsive to corticosteroid injections. Typically, in my hands, PRP around tendons is used after three corticosteroid injections, as some patients find that with suppression of inflammation sufficiently healing occurs and symptoms do not return.
More recently, PRP has been used in osteoarthritis as well. This appears to be effective because of an anabolic effect on joint cartilage as well as an effect on the nerve endings which mediate pain. Although claims are often made that PRP can build cartilage, it is my understanding that the current evidence does not conclusively show such an effect in osteoarthritis in humans. The anabolic effect would possibly slow down further development and progression of osteoarthritis; this has not been proven in human osteoarthritis either. It is clear that some patients experience good pain relief after PRP injection for osteoarthritis, at times within a few days, much faster than could be attributed to an anabolic effect on joint cartilage. Such a quick improvement in pain has been observed in the treatment of dogs and horses as well. It is likely that a significant proportion of the effect of PRP in osteoarthritis has to do with an effect on the nerve fibres responsible for the transmission of pain, perhaps through a coating effect. Regardless of the exact mechanism, several recent studies (starting around 2014) have shown that use of PRP in treatment of osteoarthritis of the knee is similar or possibly slightly better than the use of a viscosupplement, with a duration of pain relief of 10-12 months if a pain relief response is obtained. These studies do not demonstrate slow-down or reversal of the osteoarthritic process. This is currently best considered symptomatic supportive treatment, as opposed to regenerative treatment.
PRP injection is not usually combined with corticosteroid injection. I recognize that some patients strongly wish to avoid the use of corticosteroid injection in the treatment of osteoarthritis or tendonitis. This method of non-surgical treatment would be an alternative.
Side-effects include infection, which is extremely rare as discussed above. Post-injection pain does occur in approximately 20% of patients, at times severe, usually lasting a few days, on occasion longer.

In order to provide structure to your treatment, the supportive injection therapy program offered through the White Rock Orthopaedic Surgery Clinic is organized as follows:

- Clinical assessement, diagnostic imaging as applicable, etc, leading to diagnosis and treatment plan. If supportive injections are to be pursued:

- Day of injection: maximal two joints or two tendons. For deep hip joint injections, only one hip at the time. Further injections typically delayed for at least another two weeks.

- Two weeks after injection: assessment via e-mail. If concerns, assessment in office. If no concerns, another e-mail follow-up at the approximately two months mark.

- Two months after injection: assessment via e-mail. If concerns, assessment in office. If no concerns, another e-mail follow-up at the approximately four months mark.

- Four months after injection: assessment via e-mail. If concerns, assessment in office. If no concerns, office assessment at the approximately 6 months mark, with the expectation that some further investigation or intervention may be required, particularly after corticosteroid injection.

- Further follow-up via e-mail as outlined above with office assessment every 6 months.

- In extremely stable scenarios, follow-up can be less frequent. All of this is with the understanding that in case of urgency, an earlier appointment can be booked as needed.

This document provides what I consider critical information regarding injection therapy. I would be happy to discuss this further or answer questions as they arise. I would ask you to acknowledge that you have read the above document, that you understand the various issues and that the explanations are to your satisfaction. If you wish to proceed with this type of treatment, please provide consent to do so by dating and signing this document, which we will keep on file. Presence of a valid signed consent is a prerequisite to receive injections through White Rock Orthopaedic Surgery Centre. You are free to revoke this consent at any time. If the information provided above materially changes in the future, this will be presented to you for discussion and review as indicated.

Sincerely,

Arno Smit, MD, FRCSC
Medical Director
White Rock Orthopaedic Surgery Centre

I acknowledge to have read the above document. I understand the issues and I consider the explanations satisfactory. I understand that some parts of this treatment are not covered under the Medical Services Plan. By signing this document I provide consent to receive supportive injection treatment, as outlined above. I accept the policies surrounding injections at White Rock Orthopaedic Surgery Centre, and understand that these may be modified from time to time. This consent will remain valid until revoked by myself or a representative.

Date: _____

Patient signature: _____

Patient printed name: _____

Witness signature: _____

Witness printed name: _____

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